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Free **Electronic Bulletin Board** service for Public Law numbers, **Federal Register** finding aids, and a list of documents on public inspection is available on 202–275–1538 or 275–0920.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 13

RIN 3150–AD71

Program Fraud Civil Remedies; Technical Amendment

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule: technical amendment.

SUMMARY: This document corrects a paragraph numbering error contained in the Nuclear Regulatory Commission (NRC) regulations implementing the Program Fraud Civil Remedies Act of 1986.

EFFECTIVE DATE: July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Susan Fonner, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–1634.

SUPPLEMENTARY INFORMATION: As published, the NRC's Program Fraud Civil Remedies regulations contain a numbering error in the definition of ''Claim'' contained in 10 CFR 13.2. Paragraph (b)(3) of the definition should have been numbered as paragraph (c). That this was an inadvertent error is evident both from the internal wording of the definition and from the definition of ''claim'' in the Act contained at 31 U.S.C. 3801. The definition of ''claim'' in the regulation is virtually identical to the definition in the Act, except for this numbering error.

List of Subjects in 10 CFR Part 13

Claims, Fraud, Organization and function (government agencies), Penalties.

Accordingly, 10 CFR part 13 is amended by making the following corrective amendment.

PART 13—PROGRAM FRAUD CIVIL REMEDIES

1. The authority citation for Part 13 continues to read as follows:

Authority: Public Law 99–509, secs. 6101–6104, 100 Stat. 1874 (31 U.S.C. 3801–3812). Sections 13.13 (a) and (b) also issued under section Pub. L. 101–410, 104 Stat. 890, as amended by section 31001(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2161 note).

§ 13.2 [Amended]

2. In the definition of ''Claim'' in § 13.2, paragraph (b)(3) is redesignated as paragraph (c).

Dated at Rockville, MD, this 17th day of July, 1997.

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations.

[FR Doc. 97–19929 Filed 7–28–97; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM–143; Special Conditions No. 25–ANM–130]

Special Conditions: International Aviation Services, Ltd.; Boeing Model 747–SP Airplane; High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions, request for comments.

SUMMARY: These special conditions are issued for Boeing Model 747–SP airplanes modified by International Aviation Services, Ltd. These airplanes will have novel and unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that provided by the existing airworthiness standards.

DATES: The effective date of these special conditions is July 17, 1997. Comments must be received on or before August 28, 1997.

ADDRESSES: Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, Attn: Rules Docket (ANM–7), Docket No. NM–143, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; or delivered in duplicate to the Office of the Assistant Chief Counsel at the above address. Comments must be marked: Docket No. NM–143. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: Tom Groves, FAA, Standardization Branch, ANM–113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; telephone (425) 227–1503; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that good cause exists for making these special conditions effective upon issuance; however, interested persons are invited to submit such written data, views, or arguments as they may desire. Communications should identify the regulatory docket and special condition number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. These special conditions may be changed in light of the comments received. All comments submitted will be available in the rules docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this request must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. NM–143.'' The postcard will be date stamped and returned to the commenter.

Background

On August 8, 1996, International Aviation Services, Ltd. applied for a supplemental type certificate (STC) to modify Boeing Model 747–SP airplanes

listed on Type Certificate A20WE. The modification includes the installation of a 5-tube electronic flight instrument system (EFIS) that will replace the existing electro-mechanical horizontal situation indicator (HSI) and attitude director indicator (ADI). These systems, which display flight critical information, are vulnerable to high-intensity radiated fields (HIRF) external to the airplane.

Type Certification Basis

Under the provisions of 14 CFR § 21.101, International Aviation Services, Ltd. must show that the Boeing Model 747–SP, as changed, continues to meet the applicable provisions of the regulations incorporated by reference in Type Certificate A20WE, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the ''original type certification basis.'' The certification basis for the modified Model 747–SP includes 14 CFR part 25, as amended by Amendments 25–1 through 25–8 and certain later amendments, special conditions, exemptions, and optional requirements listed in the type certificate data sheet that are not relevant to these special conditions. In addition, the certification basis for the modifications, and for areas affected by the modifications, will be amended to include the following sections:

Section	Amendment	Title
25.779(a)	25–72	Motion and effect of cockpit controls.
25.1303	25–38	Flight and navigation instruments.
25.1307	25–72	Miscellaneous equipment.
25.1309	25–41	Equipment, systems, and installations.
25.1316	25–80	System lightning protection.
25.1321	25–41	Arrangement and visibility.
25.1322	25–38	Warning, caution, and advisory lights.
25.1329	25–46	Automatic pilot system.
25.1331	25–41	Instruments using a power supply.
25.1333	25–41	Instrument systems.
25.1335	25–41	Flight director systems.
25.1381	25–72	Instrument lights.
25.1501	25–42	General.
25.1529	25–54	Instructions for Continued Airworthiness.
25.1581	25–72	General.
25.1583	25–72	Operating limitations.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25, as amended) do not contain adequate or appropriate safety standards for the Boeing Model 747–SP airplane because of novel or unusual design features, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with 14 CFR § 11.49 after public notice, as required by §§ 11.28 and 11.29, and become part of the type certification basis in accordance with § 21.101(b)(2).

Special conditions are initially applicable to the model for which they are issued. Should International Aviation Services, Ltd. apply at a later date for an STC to modify any other model already included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

The Boeing Model 747–SP will incorporate a new electronic flight instrument system that performs critical functions. This system may be vulnerable to HIRF external to the airplane.

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the Boeing Model 747–SP, which require that new electrical and electronic systems, such as the EFIS, that perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, couples with electronic command and control of the airplane, the immunity of critical digital avionics systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraphs 1, or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–100 KHz	50	50
100 KHz–500 KHz	60	60
500 KHz–2 MHz	70	70
2 MHz–30 MHz	200	200
30 MHz–100 MHz	30	30
100 MHz–200 MHz	150	33
200 MHz–400 MHz	70	70
400 MHz–700 MHz	4,020	935
700 MHz–1 GHz	1,700	170
1 GHz–2 GHz	5,000	990
2 GHz–4 GHz	6,680	840
4 HGz–6 GHz	6,850	310
6 GHz–8 GHz	3,600	670
8 GHz–12 GHz	3,500	1,270
12 GHz–18 GHz	3,500	360
18 GHz–40 GHz	2,100	750

Applicability

As discussed above, these special conditions are applicable to Boeing Model 747–SP airplanes modified by International Aviation Services, Ltd. Should International Aviation Services, Ltd. apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate A20WE to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101(a)(1).

Conclusion

This action affects only certain design features on Boeing Model 747–SP airplanes modified by International Aviation Services, Ltd. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of the special conditions for this airplane has been subjected to the notice and comment procedure in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. For this reason, and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions immediately. Therefore, these special conditions are being made effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 747–SP airplanes modified by International Aviation Services, Ltd.

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high intensity radiated fields.

For the purpose of these special conditions, the following definition applies:

Critical Functions. Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on July 17, 1997.

Gary L. Killion,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–19858 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1270

[Docket No. 93N–0453]

RIN 0910–AA40

Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require certain infectious disease testing, donor screening, and recordkeeping to help prevent the transmission of the human immunodeficiency virus (HIV), and hepatitis viruses through human tissue used in transplantation. In response to comments received, FDA has clarified and modified many of the provisions of the interim rule on human tissue intended for transplantation which was published in the **Federal Register** of December 14, 1993. The final rule requires facilities engaged in the recovery, screening, testing, processing, storing, or distributing of human tissues to ensure that specified minimum required medical screening and infectious disease testing has been performed and that records documenting such screening and testing for each human tissue are available for inspection by FDA. The regulations also contain provisions for the inspection of such facilities and for retaining, recalling, or destroying human tissue for which appropriate documentation is not available.

DATES: The regulation is effective January 26, 1998. This effective date is applicable to all human tissue intended for transplantation procured on or after this date. Written comments on the information collection requirements should be submitted by September 29, 1997.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

In the **Federal Register** of December 14, 1993 (58 FR 65514), FDA issued an interim rule on human tissue intended for transplantation (hereinafter referred to as the interim rule). These regulations became effective upon the date of publication in the **Federal Register** and required human tissue in storage as of that date to be in compliance. The interim rule was issued because of evidence indicating an immediate need to protect the public health from the transmission of HIV infection and hepatitis infection through transplantation of human tissue from known donors infected with or at risk for these diseases. The movement towards regulating human tissue was accelerated by a hearing on appropriate oversight for human tissue banking chaired by Senator (then Representative) Wyden before the Subcommittee on Regulation, Business Opportunities and Technology of the Committee on Small Business held on October 15, 1993. At the hearing, representatives of persons involved in human tissue banking advocated that legislation setting forth regulatory requirements for human tissue banking be passed. There was testimony that human tissues from foreign sources were being offered for sale in the United States with little documentation as to the source of the human tissue, the cause of death, the medical conditions of the donor, or the results of donor screening and testing. This raised significant concerns about the safety and quality of some of the human tissue available for transplantation. As a result of a number of similar allegations, the agency initiated inquiries into the possibility that human tissues intended for transplantation were being supplied without appropriate infectious disease testing and medical screening. In a relatively brief period of time, the agency was able to confirm the availability for importation and distribution to the United States of

human tissue that did not follow adequate screening and testing standards to prevent transmission of infectious disease.

In the early 1990's, prior to the above-mentioned reports of the distribution of imported human tissue not following adequate screening and testing standards, the Centers for Disease Control and Prevention (CDC) reported that HIV had been transmitted through transplantation of human tissue. Based in part on the CDC report, the Assistant Secretary for Health convened a Public Health Service Work Group to evaluate the need for and type of Federal oversight that should be developed for human tissue. In its report on July 18, 1991, the Work Group recommended Federal development and publication of standards or guidance on donor screening, testing, recordkeeping and tracking procedures to reduce the risk of transmission of infectious disease. The Work Group recommended that Federal agencies, including FDA, proceed with pending regulations as ''expeditiously as possible.'' The Work Group charged FDA to ''continue to assert its jurisdiction over tissues on a product-by-product basis to ensure adequate oversight.'' The Work Group noted that investigation into the needed level of mandatory oversight for human tissue transplantation, apart from organ and bone marrow transplantation, should take place and recommended that FDA evaluate this issue. Subsequently, FDA issued the interim rule.

Since the interim rule was issued, FDA has issued 15 orders for retention, recall, and destruction of violative human tissue. In March 1995, following receipt of an order for retention, recall, and destruction that caused shipments of a firm's processed allografts to be held, a processor of human tissue filed a complaint in Federal District Court challenging FDA's interim rule and the application of internal guidance on the interim rule issued to field investigators. The court issued the plaintiff preliminary injunctive relief by enjoining FDA from detaining particular shipments of the plaintiff's tissue. The plaintiff and FDA subsequently entered into an agreement settling their dispute, and the plaintiff's complaint was dismissed.

After FDA issued the interim rule, FDA held three separate workshops to promote continuous dialogue between FDA and the human tissue industry. The first workshop, which FDA announced in the **Federal Register** of June 10, 1994 (59 FR 29950), was entitled ''Public Workshop on Human Tissue Intended for Transplantation'' and was held on June 20, 1994 (hereinafter referred to as the June 1994 workshop). An objective of the workshop was to give industry the opportunity to discuss practical concerns relating to the implementation of the interim rule. It was the intention of FDA to review and consider the discussion of these topics in the development of any future rulemaking. The comment period on the interim rule closed March 14, 1994, but was reopened until August 20, 1994, to allow interested persons additional time to submit comments on both the interim rule and the workshop.

In the **Federal Register** of February 17, 1995 (60 FR 9335), FDA announced that the Blood Products Advisory Committee, scheduled to meet on March 23 and 24, 1995, would participate in a workshop entitled ''Human Tissue Intended for Transplantation and Human Reproductive Tissue: Donor Screening and Infectious Disease Testing'' (hereinafter referred to as the March 1995 workshop). The topics discussed at the workshop were: (1) Recommendations for donor screening and infectious disease testing for human tissue intended for transplantation, (2) draft discussion points for screening and testing donors of human reproductive tissue, and (3) a draft registration form. FDA made the ''Draft Discussion Points for Screening and Testing Donors of Human Tissue Intended for Transplantation and Human Reproductive Tissue,'' and the draft establishment registration form available before and at the meeting.

In the **Federal Register** of May 24, 1995 (60 FR 27406), FDA announced a third workshop on human tissue. This workshop, entitled ''Human Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives'', was held on June 20 and 21, 1995 (hereinafter referred to as the June 1995 workshop). The purpose of this workshop was to provide an opportunity for continued discussion of the regulation of human tissue for transplantation. The workshop consisted of plenary and breakout sessions that focused on the following topics: (1) Donor screening, (2) infectious disease testing and inactivation methods, (3) voluntary standards, (4) assessment of industry practices related to tracking, (5) interactions with organ procurement organizations and procurement coordination practices, and (6) State regulatory approaches and industry practices. FDA offered a draft discussion document concerning the screening and testing of donors of human tissue intended for transplantation in advance and at the workshop. The availability of the draft document was announced in the **Federal Register** of June 20, 1995 (60 FR 32128). FDA requested that comments on the draft document be sent to the Dockets Management Branch by July 20, 1995, for consideration in the drafting of a guidance document.

In response to industry requests for clearer guidance on donor screening and in an effort to consolidate and disseminate recommendations on the screening of donors for signs and symptoms of infectious disease, FDA has prepared a document entitled ''Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation,'' the availability of which is announced elsewhere in this issue of the **Federal Register**. This guidance was prepared taking into account the issues addressed in the draft document distributed at the workshop and comments received.

The final rule takes into account comments submitted to the Dockets Management Branch, and discussions and information obtained through public participation in the three workshops. The agency is taking this action to provide clarification of the interim rule and to finalize its provisions.

B. Scientific and Legal Justification

The use of HIV antibody testing on donors of human tissue makes the human tissue inventory safer. However, it does not eliminate the ''window'' period between the time of infection and the presence of detectable levels of antibodies to HIV. Therefore, as an added safety measure FDA requires screening for behavioral and high risk information in addition to testing for infection with the virus so that the safest product will be made available. Like the HIV virus, evidence of hepatitis B and hepatitis C is determined by screening and testing human tissue donors. Since HIV and hepatitis viruses are transmitted by parenteral and sexual modes, exclusion of potentially infected donations by both screening and testing the human tissue donor has been found to be reliable and widely accepted. These viruses may be transmitted by a wide range of human tissue including solid organs, musculoskeletal and integumentary tissue, and body fluids (e.g., semen and breast milk).

FDA is issuing these regulatory requirements under the legal authority of section 361 of the Public Health Service Act (the PHS Act, 42 U.S.C. 264). This section authorizes the Secretary of the Department of Health and Human Services (the Secretary), to make and enforce such regulations as

judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from State to State. Intrastate transactions may be regulated under authority of this provision, as appropriate (see *State of Louisiana* v. *Mathews*, 427 F. Supp. 174 (E. D. La. 1977)). Section 361 of the PHS Act also provides for such inspection and destruction of articles found to be so infected or contaminated as to be sources of dangerous infection to humans, and other measures, as may be deemed by the Secretary to be necessary. Section 361 of the PHS Act has been invoked by FDA to regulate various activities or articles. For example, FDA has invoked this authority to regulate conveyance sanitation, the source and use of potable water, and milk pasteurization. The agency has also acted under section 361 of the PHS Act to prevent the transmission of communicable disease through shellfish, turtles, certain birds, and bristle brushes (see 21 CFR parts 1240 and 1250). FDA has also relied in part on section 361 of the PHS Act in issuing requirements to protect the blood supply.

Authority for the enforcement of section 361 of the PHS Act is provided for in part under section 368 of the PHS Act (42 U.S.C. 271). Under section 368(a), any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year (42 U.S.C. 271(a)). Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted (18 U.S.C. 3559 and 3571(c)). In addition, Federal District Courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act.

II. Highlights of the Final Rule

The final rule provides clarification of certain provisions of the interim rule and responds to the comments and concerns expressed. In response to comments received on the interim rule, definitions have been added or modified for the following terms: Blood component, colloid, contract services, crystalloid, donor medical history interview, establishment, importer of record, legislative consent, person, physical assessment, plasma dilution, reconstituted blood, relevant medical records, responsible person, and summary of records. The final rule further elaborates on the requirements for: (1) Criteria for using an algorithm when determining plasma dilution, (2) documents to be included in the summary of records, (3) responsibility for maintaining the records used in determining the suitability of the tissue for transplantation, (4) the relevant medical records for corneal tissue recovered under legislative consent, and (5) the shipment of tissue. The rule also describes the steps to be followed when human tissue is offered for import.

Due to the renumbering of many of the sections in the rule the following chart is being provided for comparison:

TABLE 1.—COMPARISON CHART OF FINAL AND INTERIM RULES

Final Rule (section)	Interim Rule (section)	Nature of Change
Subpart A—General Provisions		
Scope 1270.1(a)(b)(c)(d)	1270.1(a)(b)	Additional exemptions added.
Definitions 1270.3(a)–(x)	1270.3(a)–(i)	Definitions added for: (b) blood component, (c) colloid, (d) contract services, (e) crystalloid, (h) donor medical history interview, (i) establishment, (k) importer of record, (l) legislative consent, (m) person, (n) physical assessment, (o) plasma dilution, (r) reconstituted blood, (t) relevant medical records, (u) responsible person, (w) summary of records.
1270.5 through 1270.20		Removed.
Subpart B—Donor Screening and Testing		
Human Tissue Intended for Transplantation 1270.21(a)–(h)	1270.5(a)–(f)	Renumbered. Clarification of (e) summary of records, addition of (b) testing of neonate donor (g) standards for corneal retrieval, and (h) plasma dilution.
Subpart C—Procedures and Records		
Written Procedures 1270.31(a)–(e)	1270.7(a)–(c)	Renumbered. Original paragraph (c) is now paragraph (e), new paragraphs (c) and (d) require written procedures for designating and identifying quarantined tissue and for preventing contamination or cross-contamination of tissue during processing.

TABLE 1.—COMPARISON CHART OF FINAL AND INTERIM RULES—Continued

Final Rule (section)	Interim Rule (section)	Nature of Change
Records, General Requirements 1270.33(a)–(h)	1270.9(a)–(e)	Renumbered. Paragraphs (c) and (d) contain requirements for shipment of human tissue prior to and after a determination of suitability for transplantation is made. Original paragraphs (c),(d), and (e) are now paragraphs(f),(g), and (h), respectively. Paragraph (f) is amended to clarify who is responsible for record retention.
Specific Records 1270.35(a)–(d)	1270.11(a)–(c)	Renumbered. Original paragraphs (b) and (c) are now paragraphs (d) and (b) respectively. New paragraph (c) was added to require documentation of receipt and distribution of human tissue.
Subpart D—Inspection of Tissue Establishments		
Inspection 1270.41(a)–(e)	1270.13(a)–(e)	Renumbered.
1270.42(a)–(b)	none	Added steps to be followed when human tissue is offered for import.
1270.43(a)–(e)	1270.15(a)–(e)	Renumbered.

III. Comments on the Interim Rule and FDA Responses

FDA received 73 comments on the interim rule. Many comments supported FDA's effort to prevent transmission of disease through transplantation and the positive effect the interim rule had on nationwide standardization. Other comments, primarily from representatives and supporters of eye banks, objected to the interim rule. The comments stated that implementation of the rule temporarily halted transplantation operations of human tissue and argued that the industry should be allowed to continue regulating itself because of its excellent record in preventing the transmission of disease.

In general, the comments requested clarification and modification of selected sections of the interim rule, presented data supporting the suggested changes, and described burdens that particular sections would impose, e.g., the effect on cornea recovery by the requirement for a next of kin interview in States or territories with medical examiner laws, the retrospective review of tissue in storage for compliance, cadaveric specimen testing, and the import/export of human tissue from countries without certified laboratories under the Clinical Laboratories Improvement Amendments of 1988 (CLIA).

A. General Comments

1. One comment stated that the public health was threatened by the interim rule in that it contributed to an existing backlog demand for processed human tissue.

FDA recognizes that there may have been some temporary shortages of a few types of human tissue due to a small amount of human tissue in storage not being in compliance with the interim rule, but is not aware of instances where the public health was affected adversely. FDA took voluntary industry standards and State requirements into account in issuing the rule to lessen the impact of the implementation of the interim rule.

2. One comment stated that organ transplantation should be included in the scope of the interim rule and inquired as to why it was not covered.

The National Organ Transplant Act of 1984 provides for Federal oversight of the human organ transplantation system. The Health Resources Services Administration (HRSA) within the Department of Health and Human Services (DHHS) currently administers programs related to human organ transplantation. Human organs are specifically excluded from the interim rule and the final rule (new § 1270.3(j)(4)) because they are already regulated under existing Federal oversight programs and FDA does not believe that additional oversight by FDA is needed at this time.

3. Twenty-six comments maintained that eye banks adhere to strict internal standards, have an excellent track record with few documented disease transmission cases, and should not be regulated by the government.

The agency acknowledges that the trade associations for eye banks, the American Association of Tissue Banks (AATB) and the Eye Banks Association of America (EBAA) are recognized to have strict internal standards and that the eye banks have a reputation for conscientious adherence to those standards. The agency notes, however, that although corneas may have a degree of protection due to avascularity, they can, like other tissues, carry viruses and transmit communicable diseases. Therefore, FDA believes that corneas should be subject to the same regulatory oversight as other tissues. The agency would also note that the regulation will impose little or no burden for eye banks that are in compliance with the voluntary AATB and EBAA standards because these standards are substantially similar to the requirements of the regulation.

4. Two comments supported required testing by CLIA-certified laboratories.

Under provisions of the 1988 Amendments to the Clinical Laboratories Improvement Act of 1967 (CLIA '88), laboratories engaged in testing specimens in interstate commerce must meet the requirements of section 353 of the Public Health Service Act (42 U.S.C. 263a) in order to be licensed or remain licensed for testing in interstate commerce. CLIA applies to laboratories, including physicians' office laboratories, that test human specimens. Under CLIA '88,

such laboratories are subject to regulations designed to ensure the quality and reliability of medical tests they perform. Therefore, the requirement that all infectious disease testing be performed by CLIA-certified laboratories, helps ensure standardized testing on all donors of human tissue intended for transplantation.

5. One comment inquired if contract processing is permitted under the interim rule.

FDA realizes that not all human tissue establishments have the facilities to perform all manufacturing steps. It may be more cost effective for establishments to contract out some testing and processing procedures. There is no prohibition in the interim rule or final rule concerning such contract services. Therefore, contract services have been added to the definitions in § 1270.3 (21 CFR 1270.3). FDA has revised § 1270.41(a) (21 CFR 1270.41(a)) to clarify that such contract services are subject to inspections conducted by authorized representatives of FDA.

6. Two comments urged the expedited publication of the draft guidance document *Draft USPHS Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs*, that provides specific questions for use in donor behavioral and high risk information screening.

At the time of publication of the interim rule, the final version of the guidance document had not been made available. The Public Health Service (PHS) published the final guideline on May 20, 1994, in the *Morbidity and Mortality Weekly Report* (MMWR 1994:43, 1–17). FDA considered these guidelines and previous PHS guidelines in the preparation of the final rule and the guidance document that is being announced as available by FDA elsewhere in this issue of the **Federal Register**. The guidance document provides recommendations on appropriate questions, clinical evidence, and physical evidence for use in donor screening.

7. Two comments were made on alternative methods of preventing transmission of HIV–1, HIV–2, hepatitis B, and hepatitis C viruses. One comment asked that the rule provide for a waiver process based on alternative methods of viral inactivation. One of the comments added that claims of processes that result in viral inactivation or sterility should be investigated for scientific accuracy prior to exemption from any portion of these rules.

Presently, FDA is unaware of any alternative method of viral inactivation that FDA believes warrants omission of HIV and hepatitis testing. Therefore, FDA does not believe that such a change is warranted at this time. FDA is interested in public comment on this issue and will consider whether to include in future rulemaking a process for the agency to grant waivers from any regulation under part 1270 (21 CFR part 1270).

8. Two comments recommended that an expert advisory committee, to include transplant surgeons as members, be established as soon as possible to review and make recommendations for future rulemaking.

Since the time the interim rule was published, FDA has requested the Blood Products Advisory Committee (BPAC) to review data and make recommendations regarding human tissue for transplantation in addition to blood products. The agency recognizes the positive contribution of experienced professionals in providing FDA with assistance on regulatory issues and believes that the BPAC can serve in an advisory role on human tissue intended for transplantation.

On July 13, 1995, a report by the Institute of Medicine (IOM) entitled ''HIV and the Blood Supply: An Analysis in Crisis Decisionmaking'' was released. The Secretary directed this investigation in response to concerns voiced by the hemophilia community concerning events leading to the transmission of HIV to individuals with hemophilia from contaminated blood products. FDA has made certain changes to BPAC consistent with recommendations in the report. In particular, FDA has reformulated the membership of BPAC to limit industry-affiliated representation to a single, nonvoting representative. Additionally, FDA has revised the BPAC charter to expand the possibility for consumer representation.

B. Comments on Specific Provisions in the Interim Rule

FDA has revised the interim rule as a result of comments submitted to the docket. In addition, FDA on its own initiative is making changes to clarify the requirements of the rule and its application to the tissue industry. The term ''banked'' has been deleted from the phrase ''banked human tissue intended for transplantation'' wherever it appears in the regulations because FDA believes the term ''banked'' is unnecessary with respect to human tissues covered by this final rule

1. Scope (§ 1270.1)

Section 1270.1 defines the scope of the regulations governing human tissue intended for transplantation to include human tissue and establishments or persons engaged in the recovery, processing, storage, or distribution of human tissue. FDA has revised § 1270.1 by explicitly stating that screening and testing activities are subject to regulation. The final rule also clarifies that at this time the regulations do not apply to human tissue intended for autologous use. FDA is, however, currently conducting a review of human tissues that includes autologous use and is considering proposing additional regulations in this area.

9. One comment asked that practitioners in transplant establishments who only store human tissue for transplant in their own facilities be relieved from compliance with the provisions of the rule.

FDA recognizes that there are instances where human tissue is received and stored temporarily in a hospital or other clinical facility pending scheduled surgery within the same facility. FDA agrees that hospitals or other clinical facilities that only receive and store human tissue for transplantation within the same facility should not be covered by the rule and thus FDA has added this provision in § 1270.1(d) of the final rule. Those hospitals or clinical facilities that participate in the recovery, screening, testing, processing, or distribution of human tissue in addition to storage for transplantation are covered by the rule.

2. Definitions (§ 1270.3)

Section 1270.3 defines various terms used in the regulations. In the final rule FDA has clarified, revised and simplified the definitions. For clarity, FDA has added the terms ''shipment,'' and ''exportation'' to the definition of ''distribution'' (§ 1270.3(f) of the final rule). The definition of ''processing'' (§ 1270.3(p) of the final rule) has been revised by deleting the word ''potency'' and by adding that processing includes ''the inactivation or removal of adventitious agents.'' The phrase ''human tissue that has not yet been characterized as suitable for transplantation'' has been added to clarify the definition of ''quarantine'' (§ 1270.3(q) of the final rule). The definition of ''storage'' (§ 1270.3(v) of the final rule) has been simplified by deleting any reference to the facility holding the tissue. The term ''native vasculature'' has been replaced by the term ''original blood vessels'' in the definition of ''vascularized'' (§ 1270.3(x) of the final rule).

10. One comment suggested that the rule apply to normal human cells such

as hepatocytes that can be transplanted with little or no manipulation.

The agency declines to accept the comment's suggestion. The rule covers human tissue such as bone, ligament, tendons, fascia, cartilage, corneas, and skin. Hepatocytes and other cellular based therapies are regulated by FDA as biological products. (See description in ''Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products'' (58 FR 53248).)

11. One comment asked for definition of the following terms: (1) Blood component, (2) colloid or volume expander, (3) crystalloid, (4) hemodilution, and (5) pretransfusion specimen.

FDA agrees that some additional definitions should be included and is amending § 1270.3 to include definitions for ''blood component,'' ''colloid'' (volume expander), ''contract services,'' ''crystalloid,'' ''donor medical history interview,'' ''establishment,'' ''importer of record,'' ''legislative consent,'' ''person,'' ''physical assessment,'' ''plasma dilution'' (to replace ''hemodilution''), ''relevant medical records,'' ''reconstituted blood,'' ''responsible person,'' and ''summary of records.'' FDA believes that the term ''pretransfusion specimen'' is self explanatory, therefore, a definition has not been added.

12. One comment requested that the definition of ''vascularized'' that appears in § 1270.3(c) of the interim rule be clarified.

FDA agrees that the definition of vascularized should be clarified and has revised the definition.

13. Two comments requested a revision to the definition of human tissue to specifically exclude human organs and those human tissues that have been chemically or biophysically altered, such as heart valves.

The definition of human tissue found in § 1270.3(b) of the interim rule (§ 1270.3(j) of the final rule) contains a specific exclusion for vascularized organs (kidney, liver, heart, lung, pancreas, or other vascularized human organs). Allograft heart valves, dura mater allografts, epikeratophakia lenticules, preserved umbilical cord vein grafts, and various skin and bone products that have been chemically or biophysically altered are currently regulated as devices under the authority of the Medical Device Amendments of 1976 (Pub. L. 94–295) and are therefore excluded from this definition of human tissue. However, FDA is considering the regulation under part 1270 of human heart valve allografts and certain other tissues now regulated as devices. To allow all interested persons to comment on this regulatory change, FDA intends to provide notice and request for comment on such regulation in the **Federal Register** at a future date. Human tissues that are processed in ways to only reduce infectivity or preserve human tissue integrity are regulated under part 1270.

3. Donor Testing (§ 1270.21)

Section 1270.5 of the interim rule specifies the requirements for testing donor blood specimens for evidence of communicable viruses, i.e., HIV–1, HIV–2, hepatitis B, and hepatitis C. It requires that these tests be done using FDA licensed test kits approved for such use by FDA and performed in a laboratory certified under CLIA. In the final rule, FDA has deleted the terms ''blood'' and ''serological'' and the name of the communicable virus has been listed in place of a specific marker test. This change has been made to allow for future advancement in science and technology which could cause a change in the appropriate test methodology. Section 1270.5(e) of the interim rule has been split into § 1270.21(f) and (g) of the final rule, in part to clarify the revised requirements for corneal tissue retrieval.

14. One comment inquired if human tissue would be considered suitable for transplantation if a repeatedly reactive screening test for any of the viral marker tests was negative by confirmatory testing. Some comments have encouraged FDA to allow the use of tissue for which blood specimens tested repeatedly reactive for hepatitis B surface antigen (HBsAg), if the results of confirmatory neutralization testing do not confirm the results of the screening.

FDA does not concur with this suggestion. With current tests, early HIV, hepatitis B virus, and hepatitis C virus infections can be missed by the respective confirmatory test due to differences in the sensitivity of the tests, albeit at a low frequency. The agency is clarifying in the final rule, that suitability of human tissue shall be determined by the results of screening tests for the required viral markers. The rule requires that the donor be free of evidence of HIV, hepatitis B, and hepatitis C. A repeatedly reactive screening test for any of the viral markers indicates that the donor may have been exposed to and infected with the particular virus. Any indication of the possibility of infection must be taken into consideration when determining the suitability of the human tissue. The use of screening tests in determining the suitability of the donor of human tissue intended for transplantation is clarified in § 1270.21(a) of the final rule which specifically identifies ''screening * * *'' as the required test. Therefore, tissue that is repeatedly reactive is not suitable for use even if confirmatory tests are negative. In addition, if the tissue establishment becomes aware of indeterminate, repeatedly reactive, or positive test results relative to HIV or hepatitis, even if the tests are not specifically required by the final rule, then the tissue is considered not suitable for transplantation.

15. Seven comments questioned the validity of certain viral marker tests using cadaveric blood specimens. Concern was expressed over the inadequate data that exists on the testing of cadaveric blood specimens using FDA licensed screening kits for viral markers and guidance was requested in determining the suitability of the donor.

FDA is aware of the need to clarify the appropriateness of using cadaveric specimens, i.e., a blood specimen taken from a donor whose heartbeat has ceased, with the currently licensed test kits. Generally, the concern is that test results based on testing of cadaveric blood specimens that exhibit some degree of hemolysis and/or lipemia may not be accurate. FDA is working with manufacturers towards validation of assays for cadaveric specimen use. Screening tests that have been approved for testing cadaveric blood are to be used, once FDA approval has been given and the labeling of the test kit has been modified to specifically indicate the use of cadaveric blood specimens.

16. One comment dealt with a letter issued by CBER on December 28, 1993, to the tissue industry (hereinafter referred to as the December 1993 letter). This letter, which was intended to provide clarification to the industry regarding HIV–2 testing, contained the statement, ''as long as the tissue was tested by the best available test methods at the time, and the newly available test methodology was adopted in a timely manner, the tissue continues to be suitable for transplant.'' The comment said this statement may be misleading because it could be interpreted to include other newly licensed tests in addition to tests for HIV–2.

Because the December 1993 letter addresses HIV–2 testing only, FDA does not believe the statement cited by the comment could be easily misinterpreted as referring to tests for other infectious agents.

17. Three comments requested further explanation of the approval requirements for laboratories doing screening tests on donor specimens. Specifically requested, was clarification

of the term ''registered and certified under CLIA'' and recognition, by the Health Care Finance Administration (HCFA), of accreditation by an acceptable alternative inspection organization.

Shortly after publication of the interim rule, FDA provided guidance regarding § 1270.5(b) in the December 1993 letter. Laboratories have the option of coming under the jurisdiction of HCFA directly, or indirectly by way of accreditation by a private accreditation organization approved by HCFA for ''deemed status,'' or by being located in a State approved for exemption under CLIA. In the December 1993 letter, FDA recognized that many laboratories had been registered but not yet certified under CLIA, because: (1) They had not yet been surveyed (inspected) by HCFA or one of its agents; (2) they had been surveyed but had not yet received their certificate of compliance; or (3) the accrediting organization performing the survey had applied for but had not yet received approval by HCFA for ''deemed status'' under the 1988 amendments. During this transition period, FDA stated that its preliminary interpretation was that a laboratory was suitable for performing the testing required by the interim rule provided: (1) The laboratory had an active and current history of being surveyed by HCFA or one of its agents, by a private accrediting organization, or an organization whose approval by HCFA was pending; (2) the laboratory was in good standing with HCFA, and if applicable, FDA, in that there was no regulatory action either pending or in effect that would limit the laboratory's ability to perform the types of tests that are required in the interim rule; and (3) the laboratory was registered with HCFA at that time. Since the publication of the interim rule, HCFA has completed the first survey of registered laboratories. All laboratories that have met the inspection criteria have been issued certification under CLIA. Thus, laboratories must now be certified under CLIA.

18. One comment on § 1270.5(a) (§ 1270.21(a) of the final rule) urged that tests such as those run on lymph node tissue or vitreous humor be considered in the absence of an appropriate blood specimen.

In § 1270.21 of the final rule, FDA has deleted the identification of blood as the source of specimen required for infectious disease testing, recognizing advances in technology and the possibility of future approval of viral marker testing (used in determining donor suitability) that may utilize alternative specimen sources. At this time, blood is the only specimen approved for use with FDA licensed viral marker tests to determine donor suitability.

19. One comment on § 1270.5(b) (§ 1270.21(c) of the final rule) asserted that the rule discriminates against importers of human tissue because they are unable to comply with the requirement for testing by a CLIA certified laboratory.

During a congressional hearing held on October 15, 1993, testimony was given with respect to an increase of unsuitable human tissue derived from foreign sources being offered for sale in the United States by individuals unwilling to declare the actual source of the human tissue, to provide documentation as to the cause of death, the medical records of the donor, the results of donor screening and testing, or to furnish specimens of donor serum for testing. Human tissue imported from outside the United States must meet the same standards of donor screening, testing, and tissue recovery applied to all domestic human tissue because of the potential for the transmission of communicable diseases. When the interim rule was published on December 14, 1993, there were no CLIA certified testing laboratories in foreign countries. Although these facilities were unavailable at the time, foreign establishments were not prohibited from using domestic CLIA certified laboratories for performing the required testing. Any laboratory, foreign or domestic, may apply for certification under CLIA. The proficiency of the laboratory performing the required testing is a key element in assuring the safety of human tissue. Inspection and regulation under CLIA helps to ensure that the laboratory is proficient and competent to perform the required tests accurately. Therefore, FDA's requirements are not intended to discriminate against foreign importers, but are an attempt to help ensure that foreign human tissue meets the same standards as human tissue procured in the United States for transplantation.

4. Plasma Dilution

20. Under section 1270.5(d) (§ 1270.21(h) of the final rule), human tissue from donors whose blood specimen may be diluted sufficiently to affect infectious disease test results is unsuitable unless the specimen is assessed for acceptability using an established procedure to calculate dilution (algorithm). One comment suggested revising the term ''hemodilution'' to ''plasma dilution'' to accurately describe the dilutional component because it is the infused plasma or fluid which dilutes the donor's plasma or serum used for testing, not the red cell volume.

FDA agrees with the comment and is amending § 1270.5(d)(1) § 1270.21(h)(2) in the final rule) to use the term ''plasma dilution.''

21. Two comments on § 1270.5(d) (§ 1270.21(h) of the final rule) proposed revisions to include specific factors for consideration in determining the suitability of human tissue when the possibility of plasma dilution exists. The comments noted that FDA did not address generally accepted criteria for making the determination of plasma dilution.

FDA recognizes that the interim rule did not address different factors such as amount of blood loss, renal output versus input of fluids, time of sampling in relation to transfusion/infusion, and volume transfused/infused in determining plasma dilution. Section 1270.21(h) of the final rule is revised to recognize that an algorithm may be used to ensure that there has not been plasma dilution sufficient to affect test results. Plasma dilution is further discussed in comment 25 of this document. FDA also notes that factors regarding the selection of an appropriate algorithm for determining plasma dilution are discussed in the Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation. The notice of availability of this guidance document may be found elsewhere in this issue of the **Federal Register**.

22. One comment on § 1270.5(d)(1) (§ 1270.21(g)(2)(i) of the final rule) inquired if a pretransfusion/infusion specimen was sufficient for testing or whether a posttransfusion/infusion specimen should also be tested.

A posttransfusion/infusion specimen is not necessary when an adequate pretransfusion/infusion specimen is available. If a pretransfusion/infusion specimen is unavailable for testing, then for the tissue to be assessed for suitability, a posttransfusion specimen must be assessed for plasma dilution using an algorithm prior to testing.

23. Five comments on § 1270.5(d)(1) (§ 1270.21(g)(2) of the final rule) discussed the difficulty in obtaining pretransfusion/infusion specimens because many potential donors arrive at the emergency room in the process of being transfused with blood or infused with fluids, thus eliminating the possibility of obtaining a pretransfusion/infusion specimen.

The agency realizes a pretransfusion/infusion specimen is not always available. In those cases where the specimen is unavailable, an algorithm to determine if plasma dilution may affect

test results should be applied to determine donor suitability. The establishment's standard operating procedures (SOP's) should outline this algorithm and the measures for determining donor suitability.

24. Two comments requested clarification of specific circumstances when plasma dilution should be considered and what specific tests would be affected by plasma dilution.

When a pretransfusion/infusion specimen is unavailable, FDA believes the following criteria should be considered in evaluating the need for using an algorithm to determine if plasma dilution is sufficient to affect infectious disease test results: (1) Blood loss is known or suspected to have occurred; (2) the tissue donor was transfused or infused and an adequate pretransfusion/infusion specimen is not available for infectious disease testing; (3) if preceding the collection of the donor specimen in adult donors, more than 2,000 milliliters (mL) of: whole blood, reconstituted blood, red blood cells, and/or colloids have been administered within the previous 48 hours and/or; crystalloids have been administered within the previous one hour; or any combination of these has occurred; and (4) in any donor 12 years of age or less, any transfusion/infusion has occurred. Once this information is reviewed and the determination is made that the 2,000 mL is exceeded or the donor is 12 years of age or less, the tissue is considered unsuitable until an algorithm defined in the tissue establishment's SOP's is used to assess whether the dilution affected the test results.

25. Fourteen comments on § 1270.5(d)(2) (§ 1270.21(h)(2)(ii) of the final rule) requested clarification and guidance on specific aspects of an acceptable algorithm in evaluating plasma dilution. One comment stated that, in the absence of science, further rulemaking should not include an arbitrary cutoff. In particular, the comments asked FDA to elaborate on: (1) Who is responsible for determining the parameters of the algorithm; (2) the type of blood, blood components, and fluids to be included or excluded; (3) the time period that is to be taken into consideration and the basis on which it is calculated; (4) the unit of measurement to be used; (5) the maximum volume allowed; and (6) the consideration given to output versus input.

FDA is not prescribing who may prepare the algorithm. It may be prepared by any responsible person with adequate training and understanding of the principles of plasma dilution. FDA discusses the criteria for using an algorithm to determine plasma dilution in comment 24 of this document, and is providing additional information on a suitable algorithm in the Guidance for Screening and Testing Donors of Human Tissue Intended for Transplantation announced elsewhere in this issue of the **Federal Register**. The information in the guidance document is based on available scientific evidence and was the focus of the workshop held in June 1995.

The discussion of an algorithm for determining plasma dilution in the guidance document is based on the calculation of blood volume and plasma volume in relation to the donor's body mass. Where blood loss has occurred or is suspected, and a pretransfusion/infusion donor specimen is not available,§ 1270.21(h) provides for use of an algorithm when the transfusion/infusion of more than 2,000 mL of whole blood, reconstituted blood, red blood cells, and/or colloids in the previous 48 hours and/or crystalloids within the previous one hour, or any combination, has occurred in the stated time periods prior to the collection of the specimen. The time periods recommended by the algorithm are based on the safety record of voluntary standards in the tissue industry employing such a time period and on a 50 percent volume dilution of blood or plasma. Transfused/infused products have been broken into categories for the purpose of calculating the volumes transfused/infused. They are blood, colloid, crystalloid, and a combination of these categories.

FDA believes and has included in the regulations at § 1270.21(h) that if the following conditions are exceeded in a circumstance of blood loss and replacement in an adult, or transfusion/infusion in a child 12 years of age or less, the tissue shall be determined not suitable for transplantation. The agency currently believes that transfusion/infusion of greater than one blood volume in the case of blood replacement or greater than one plasma volume in the case of colloid and crystalloid infusion, could make infectious disease testing results unreliable due to plasma dilution.

TABLE 2.—BLOOD AND PLASMA VOLUME CALCULATION

Category infused	Product(s) included in category	Hours prior to specimen collection	Calculated[1] volume administered
Blood	Blood unit labeled as ''Whole Blood,'' Blood unit labeled as ''Red Blood Cells,'' Reconstituted blood[2]	Within 48 hours	> one blood volume
Colloid	Plasma, platelets, albumin, hetastarch, dextran	Within 48 hours	> one plasma volume
Crystalloid	Saline, dextrose in water, Ringer's lactate, other balanced electrolyte solutions	Within 1 hour	> one plasma volume
Blood and colloids and/or crystalloids	See all of the above	Within 48 hours and within 1 hour	> one blood volume (or if the calculated volume for colloids only, within 48 hours of collection and/or crystalloids within 1 hour of collection is > one plasma volume)
Colloids and crystalloids	See above for colloid and crystalloid	Within 48 hours and within 1 hour	> one plasma volume

[1] Recommended methods for blood and plasma volume calculations may be found in the ''Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation.''

[2] Reconstituted blood means the extracorporeal resuspension of a blood unit labeled as ''Red Blood Cells'' by the addition of colloids and/or crystalloids to produce a hematocrit in the normal range.

5. Screening

26. Section 1270.5(e) (§ 1270.21(f) of the final rule) requires that in order to determine the suitability of human tissue for transplantation, the identity of the donor shall be ascertained and the relevant medical records shall be reviewed to assure freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, and HIV infection. One comment requested that the medical history include all available medical, coroner, and autopsy records, both written and those communicated orally by health care practitioners.

FDA agrees that oral communications specific to the donor's relevant medical history could affect donor suitability and should be documented because they are an integral part of the donor testing and screening process. This information should be recorded by a responsible person and should serve as an adjunct to other available information and records required by new § 1270.21. FDA has included a definition for ''relevant medical records'' in § 1270.3(t) which is consistent with the comment.

27. Twenty comments on § 1270.5(e) (§ 1270.21(f) and (g) of the final rule) expressed concern that the requirement for a donor medical history interview (formerly the Next-of-Kin interview in the interim rule) as part of the relevant medical records, would make it more difficult to procure corneas under legislative consent (formerly Medical Examiner Law in the interim rule and defined in § 1270.3(h) of the final rule). The comments suggested that the donor medical history interview for corneas procured under legislative consent be waived. One comment proposed using the ''all available information'' standard in determining suitability of corneas for transplantation. In an opposing viewpoint, six comments disagreed with a waiver of donor medical history interviews for corneas procured under legislative consent. The latter stated that corneas procured as a result of legislative consent do not meet industry standards and diminish the ability of transplant professionals to effectively promote the altruistic benefits of donation. These comments endorsed regulation of corneas because corneal tissue does transmit disease and should be regulated as strictly as other tissue.

After reviewing the numerous comments on the interim rule and the discussions at the workshops, FDA acknowledges the need for flexibility in the procurement of corneal tissue under legislative consent. Where corneas are procured under legislative consent, FDA has modified the regulations in the final rule to accept as sufficient a physical assessment of the donor in the absence of a donor medical history interview for behavioral and high risk information. Even though corneas may have a degree of protection due to avascularity, FDA notes that it is possible that viruses may be present in donor corneal tissue. Therefore, the agency believes that this modification underscores the importance of additional information gathering in determining the suitability of a donor. Negative viral marker test results for HIV and hepatitis, and review of other available information in addition to the physical assessment, will continue to be a requirement. However, if additional tissue other than cornea is recovered from the same donor, then a donor medical history interview is required. Based on the recommendation of the PHS ''Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs'', (MMWR, May 20, 1994) FDA is requiring under new § 1270.21(g) documentation in the summary of records that corneal tissue was procured under legislative consent so that the transplant surgeon will be aware that: (1) A donor medical history interview was not obtained, (2) a physical assessment of the donor for evidence of high risk behavioral signs of HIV and hepatitis infection had been made, and (3) the tissue was determined to be suitable in the absence of the donor medical history interview.

28. One comment on § 1270.5(f) (§ 1270.21(e) of the final rule) stated that the requirement that a full set of records physically accompany each of the approximately 300,000 allografts distributed annually in the United States was superfluous as well as unduly burdensome and expensive.

FDA believes that the comment has misinterpreted the meaning of § 1270.5(f). Human tissue that is determined to be suitable for transplantation per § 1270.9(b) (§ 1270.21(e) of the final rule) must be accompanied by copies of original records, indicating that all infectious disease testing and screening under § 1270.5 (§ 1270.21 of the final rule) has been completed, reviewed by the responsible person, and found to be negative. The agency has routinely accepted completed summaries of such records as long as the summary contains the identity of the testing laboratory, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of the human tissue for transplantation.

After review, FDA finds the recordkeeping requirements of the rule no more burdensome or potentially costly than the standards established by the American Association of Tissue Banks or the Eye Bank Association of America which require labeling and package inserts to accompany a shipment of human tissue.

6. Written Procedures (§ 1270.31)

Section 1270.7 (§ 1270.31 of the final rule) sets forth the requirements for written procedures for infectious disease testing, and obtaining, reviewing, and assessing the relevant medical records of the donor.

The agency has added § 1270.31(c) and (d) requiring written procedures for the designation and identification of quarantined tissue, and for the prevention of contamination or cross-contamination of tissues during processing. Because HIV and hepatitis screening and testing of the donor may be incomplete at the time of processing, and to maintain the separation of suitable tissue from that not yet determined to be suitable or tissue that has been determined to be unsuitable for transplantation (which is the intent of the concept of ''quarantine'' as it is used in the final rule), FDA is requiring that these written procedures be prepared and followed. FDA is also requiring that the written procedures for preventing the contamination or cross-contamination by tissues during processing be validated. These requirements will facilitate the timely processing of tissue when necessary (e.g., skin and cornea) while maintaining quarantine and continuing current good practices performed by industry in daily processing.

29. Two comments asked for a clearer statement that the written procedures and records requirement of §§ 1270.7(a) and 1270.9(a) are the responsibility of the laboratory where the tests are run.

FDA has amended the requirements of § 1270.9 (§ 1270.33 of the final rule) to state that the person or establishment making the determination regarding the suitability of human tissue is responsible for retaining all testing and screening records used in making the

determination of suitability for transplantation. FDA believes that the person (as defined in § 1270.3(m) of the final rule) or establishment (as defined in § 1270.3(i) of the final rule) that has made the determination of suitability should have and retain the testing and screening records used in making the determination. The individual records must also be retained by the establishment performing the work being recorded. For human tissue that is determined to be suitable, the person or establishment receiving the human tissue should receive a summary of records (as described in § 1270.1(w)) used in determining the suitability of the donor. The summary should identify the responsible person, in addition to the person or establishment that made the determination that the human tissue is suitable for transplantation in accordance with § 1270.21(e). Other than having the summary, FDA does not expect the transplant institution to receive complete documentation regarding the suitability of the donor. If FDA has questions regarding donor suitability, the person or establishment that made the determination of donor suitability will ordinarily be contacted. That person or establishment is responsible for having all records used in making the determination. With respect to testing records, the testing laboratory should retain records of the test results and the interpretation of the test results. Copies of the interpretation of the test results should also be provided to, and retained by, the person or establishment making the final determination of donor suitability.

30. Three comments on § 1270.7(c) (§ 1270.31 of the final rule) requested clarification on which organization's SOP would be acceptable and suggested that the agency require each facility to have its own SOP that includes processing, storage, and final disposition of human tissue.

The regulations require each facility to prepare and follow written procedures for testing and screening of human tissue. In § 1270.31 of the final rule, written procedures are required for all significant steps involved in the infectious disease testing process which shall conform to the manufacturers' instructions for use contained in the package inserts, and for all significant steps in obtaining, reviewing, and assessing for completeness the relevant medical records of the donor. Any deviation from the establishment's written procedures shall be recorded and justified. FDA investigators review an establishment's written procedures during an inspection, to evaluate whether the SOP's are consistent with the regulations, and to determine that the establishment is following the procedures documented in the SOP's. A detailed and complete SOP ensures uniformity and consistency for each procedure performed. Each establishment may develop its own written procedures or adopt those in a manual prepared by another organization, as long as the procedures satisfy the requirements set out in the regulations. Because each establishment differs, an establishment using procedures developed by another establishment or organization should evaluate those procedures to determine whether they are adequate or need to be revised by that establishment. The responsibility for ensuring adequacy of procedures and compliance rests with the individual establishment regardless of the source of its procedures.

7. Records, general requirements (§ 1270.33) and Specific records (§ 1270.35)

Sections 1270.9 and 1270.11 of the interim rule (§§ 1270.33 and 1270.35, respectively of the final rule) set forth the general and specific requirements for the maintenance of records. Under § 1270.33(c), all human tissue that is to be processed or shipped prior to the determination of donor suitability must be under quarantine, accompanied by records identifying the donor, and identifying the tissue as not determined to be suitable for transplantation. All human tissue found suitable for transplantation must be accompanied by a complete summary of records, or copies of the original records, documenting that all infectious disease testing and screening has been completed, reviewed by the responsible person, and identified as determined to be suitable for transplantation. The summary of records also lists all the available records used in determining the suitability of the donor so that the originals of these records can be accessed, if necessary. These records include the donor medical history interview, the relationship of the person interviewed to the donor, the physical assessment of the donor, autopsy or coroner records, hospital records, police records, and any other available record used to document the suitability of the donor. If only corneal tissue was procured under legislative consent in the absence of a donor medical history interview, the accompanying summary of records shall document that: (1) A donor medical history interview was not obtained; (2) a physical assessment of the donor for evidence of high risk behavior and signs of HIV and hepatitis infection had been made; and (3) the tissue was determined to be suitable in the absence of the donor medical history interview. Under § 1270.9(c) (§ 1270.33(f) of the final rule) the person or establishment making the determination regarding the suitability of human tissue is responsible for retaining the completed records and making them available to FDA upon their request.

Section 1270.35(c) of the final rule has been added to complete the accounting of the inventory between determination of suitability (§ 1270.35(a) and (b)) and the final disposition of the human tissue (§ 1270.35(d)), e.g., the destruction of unsuitable tissue, nonclinical research use, or distributed for transplantation. The interim rule required the documentation of the records used in determining the suitability of the human tissue, and the destruction or disposition of unsuitable human tissue. The final rule requires in § 1270.35(c) documentation of the receipt and/or distribution of human tissue.

31. One comment recommended that the facility that made the final determination of donor suitability and retrieved the human tissue be required to maintain the medical history and testing records for each donor.

Retrieval and determination of donor suitability are often done by separate facilities, therefore, FDA has modified the language in § 1270.9(c) (§ 1270.33(f) of the final rule) to require the maintenance of records under § 1270.5 (§ 1270.21 of the final rule), including all testing and screening records, by the person or establishment making the determination regarding the suitability of human tissue. Persons or establishments performing operations that would generate documentation that has a bearing on a donor's suitability would retain that documentation and make it available during an FDA authorized inspection.

32. Two comments urged FDA to continue to require record retention for 10 years or until the expiration date of the human tissue, which could be longer than 10 years, but in any event no less than 10 years.

FDA agrees with the comments and has modified § 1270.33(h) to require the retention of records for a period that extends at least 10 years beyond the date of transplantation, if known, distribution, disposition, or expiration of any dating period related to the human tissue, whichever is latest.

33. One comment stated that the definition for required exclusions due to the presence of risk behaviors for certain diseases should be at all times consonant with the recommendations of

the CDC and the human tissue bank professions.

FDA has developed guidance on behavioral and high risk information, taking both the CDC's recommendations and those of the human tissue bank professions into account. At the June 1995 workshop, FDA distributed a draft document, which was also made available to the general public, discussing screening and testing issues. Representatives from CDC participated in all three workshops and FDA has based its recommendations for testing and screening on the PHS guidelines published in the *Morbidity and Mortality Weekly Reports* of April 1991, and May 1994 and public comment submitted in response to the workshop.

In conjunction with this rule, FDA is issuing a guidance document concerning the screening and testing of donors of human tissue intended for transplantation. FDA developed this document taking into account the recommendations of PHS, the Medical Standards of the Eye Bank Association of America, the American Association of Tissue Banks and comments from other interested persons.

8. Inspections (§ 1270.41)

Section 1270.13 (§ 1270.41 of the final rule) addresses the inspectional process. Establishments covered by the regulations include those establishments that recover, screen, test, process, store, or distribute human tissue and include those establishments performing such activities under contract. In large part, inspections of tissue establishments are conducted in the same manner as inspections of firms dealing in other FDA regulated commodities. FDA is presently assessing its inspectional procedures and the extent to which the agency can work with other qualified organizations to make best use of limited resources.

FDA investigators cover several major areas during an inspection. All facilities are subject to examination, including any facility contracted by the primary facility such as testing laboratories, contract sterilizers, or off-site storage facilities. The investigators may examine any human tissue at the firm to observe, for example, whether it is appropriately quarantined, identified, and stored. The inspections generally will focus on a review of required records. Employees may be interviewed regarding their performance of regulated activities. At the end of the inspection, if possible violations of the regulations are found, the FDA investigator will issue to the responsible person at the establishment a list of ''Inspectional Observations'' (Form FDA–483), describing the observations of the investigator that represent an observed or potential problem with the facility or tissue. After the report of the investigator is reviewed, FDA may issue additional correspondence to the establishment describing the violations to the regulations and requesting appropriate followup action.

FDA intends to continue to inspect regulated establishments, both foreign and domestic, when deemed necessary by the agency to ensure that human tissue is screened and tested to reduce risk of HIV, hepatitis B, or hepatitis C. Frequency of inspection after an initial inspection may depend on the extent of any violations found and will be at the agency's discretion.

34. One comment on § 1270.13 (§ 1270.41 of the final rule) asserted that the provision which allows investigators to question personnel of the establishment as the investigator deems necessary is inappropriate under the governing case law. The comment cited *Donovan* v. *Dewey*, 452 U.S. 594 (1981); *Stark* v. *Wickard*, 321 U.S. 559 (1944), and *Ernst* v. *Hochfelder*, 425 U.S. 185 (1976) to support this assertion.

FDA disagrees with the interpretation of these three cases in the context of the governing statutory authority, the PHS Act. Section 361 of the PHS Act authorizes the Secretary to issue and enforce regulations to control communicable diseases, and it provides for such inspection and destruction of articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, that may be necessary. These other measures include the use of routine inspections and the questioning of personnel during such inspections. The FDA inspector may question the firm's personnel to determine if the staff is familiar with and following the firm's written SOP's.

35. One comment on § 1270.13(e) (redesignated as § 1270.41(e) of the final rule) asked FDA to clarify whether the FDA investigator or a human tissue bank official is responsible for ensuring that records to be copied are suitably expurgated. The comment also asked for guidance on the scope and meaning of ''suitably.''

FDA has revised § 1270.41(e) of the final rule to clarify that FDA will follow its existing procedures regarding disclosure of documents. Under these procedures, FDA takes necessary precautions to protect the privacy of names of tissue donors or recipients prior to public disclosure. These procedures are set forth in 21 CFR part 20. See e.g., 21 CFR 20.63. FDA recognizes the sensitive nature of the information that would identify a human tissue donor or recipient. FDA may copy records containing identification of the donors or recipients if such records are needed for example, to document the distribution of potentially infectious human tissue.

9. Human Tissue Offered For Import (§ 1270.42)

Because some human tissue used for transplantation in the United States is obtained from foreign sources or is processed in foreign facilities and because of requests for clarification of requirements for such tissue, FDA has added § 1270.42 to clarify the administrative steps for the importation of tissue into the United States. Human tissue that has been recovered from sources outside the United States can enter the country, and tissue that has been recovered from sources in the United States that has been sent outside the United States for processing can reenter the country consistent with the provisions of §§ 1270.33 and 1270.42. For tissue imported prior to the determination of donor suitability, the tissue must be accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation. For tissue determined to be suitable for transplantation, the tissue is to be accompanied by a summary of records, or copies of the original records, indicating that all infectious disease testing and screening under § 1270.21 has been completed, reviewed by the responsible person, and found to be negative. Tissue that has been determined to be suitable for transplantation must also be identified. As with other imports, the importer of record (as defined in § 1270.3(k) of the final rule) for human tissue must notify the District Director of FDA having jurisdiction over the port of entry when the articles are offered for import. The tissue must be held in quarantine until and unless the article is released by FDA. Human tissue that is offered for import and is found to be in violation of part 1270, is subject to recall and destruction in accordance with § 1270.43 of the final rule.

10. Retention, Recall, and Destruction of Human Tissue (§ 1270.43)

Section 1270.15 of the interim rule (§ 1270.43 of the final rule) describes the procedures for the retention, recall, and destruction of human tissue upon a finding that the human tissue may be in violation of the regulations.

36. One comment on § 1270.15 (§ 1270.43 of the final rule) requested that the rule be clarified to state that

when a part 16 (21 CFR part 16) hearing has been requested, human tissues need not be destroyed until the hearing is held.

FDA has clarified § 1270.43(e) to state that any possible destruction of human tissue would be held in abeyance pending resolution of the hearing request. Under the provisions of § 16.24(d), the Commissioner of Food and Drugs (the Commissioner) may take action pending a hearing that is necessary to protect the public health. FDA is, however, sensitive to the potential economic consequences that would result from the immediate destruction of potentially violative human tissue. Any human tissue listed in such an order must be held in quarantine and cannot be released prior to the resolution of a hearing request and receipt of written notice from FDA. If destruction is warranted, the destruction of the human tissue is to be conducted under the supervision of a designated FDA official.

37. One comment asked that FDA clarify the ''may be in violation'' language in the recall and destruction part of the rule, particularly with respect to what triggers the finding of a violation.

The procedures for retention, recall, and destruction in § 1270.43 will be used only when the agency deems it necessary to ensure the suitability of human tissue for transplantation. FDA intends to invoke § 1270.43 of the final rule when there is evidence of a violation related to tissue suitability, such as the source of the human tissue, the adequacy of the testing or screening of the human tissue, the completeness of the records accompanying the human tissue, the adequacy of donor selection, and/or the attention given to the possibility that the donor was at a high risk for HIV or hepatitis.

C. Comments on Legal Issues

38. Five comments objected to the immediate effective date of the interim rule and questioned why such a measure was taken. Four comments objected to the required retrospective application of the interim rule, in that it applied to human tissue in storage upon the effective date, which may have been collected and tested before the effective date of the interim rule.

The Administrative Procedure Act (the APA) (5 U.S.C. 551 *et. seq.*) governs the issuance of rules by executive agencies. The APA's requirement of notice and comment prior to the implementation of a rule may be dispensed with when the agency for ''good cause'' finds that the procedures are ''impracticable, unnecessary, or contrary to the public interest.'' (See 5 U.S.C. 553(b)(B).)

In the preamble to the interim rule (58 FR 65514 at 65518), FDA described its good cause for proceeding directly to an interim rule. Specifically, the agency stated that the Commissioner found that the use of prior notice and comment rulemaking was ''contrary to the public interest'' because of the ''unnecessary risk of transmission of HIV infection and hepatitis infection from shipment and transplantation of human tissues derived from inadequately tested or screened donors.'' During an investigation prior to the promulgation of the interim rule, FDA investigators learned of the availability, importation, and distribution of musculoskeletal tissue materials that had not been adequately screened or tested for HIV, hepatitis B, and hepatitis C. This investigation illustrated the need for swift action to reduce the risk to the public health. Because of the public health risk posed by the inadequately tested or screened tissues, FDA applied the regulations not only to tissues screened after the effective date but also to human tissue remaining in storage for transplantation.

As previously stated, FDA provided opportunities for public comment following the promulgation of the interim rule and has considered those comments and the agency's experience in developing the final rule.

The final rule will have an effective date of 180 days after the date of publication and will apply to human tissue intended for transplantation procured on or after the effective date. For tissue procured prior to the effective date of the final rule, the interim rule applies.

39. One comment urged Federal preemption of State and local regulations on donor suitability, testing and labeling of human tissues.

FDA declines to take such a measure because the agency is not aware of any compelling reason that State regulatory authorities should be preempted at this time. The rule provides the minimum criteria necessary to help ensure tissue safety, and States are free to add additional requirements that they believe are warranted.

D. Comments on Economic Issues

40. Two comments on the economic impact in the preamble to the interim rule stated that the rule would result in an increase in the human tissue processing fee that the recipient must pay. In addition, one of the two comments stated that the number of human tissue transplants mentioned by the agency may be inaccurate and human tissue banking activities generate $59 million rather than $100 million per year.

FDA has considered the data provided in these comments in finalizing the regulations. The comments did not, however, provide the agency with figures that would illustrate an increase in the human tissue processing fee.

41. Three comments stated that the implementation of the regulations will drive the cost of corneal transplant beyond the means of the average person.

These comments did not provide data to support their contention. FDA's intention is to make tissue that is available for transplantation safer. The Eye Bank Association of America Statistical Report for 1994 does not support the premise that there has been any decrease in the availability or transplantation of corneal tissue. Both the total number of donations and the total number of transplants have increased during 1994 under the Interim Rule. However, as discussed in comment 27, FDA acknowledges the need for flexibility and has modified the requirement for corneas procured under legislative consent when there is no medical history interview available.

E. Requests for Additional Regulations

42. Five comments asked FDA to regulate all human tissue banking efforts including musculoskeletal, skin, eye, reproductive tissue, blood vessel, bone marrow, heart valves, and hospital surgical bone banks.

This rule does not apply to reproductive tissue, bone marrow, human milk, and heart valves under part 1270. Heart valves are already regulated by FDA as medical devices. HRSA administers the program for the National Bone Marrow Donor Registry. As noted in comment No. 8, in the near future, FDA is considering proposing additional regulations governing the use of human tissue and is considering whether to expand the scope of the rule to cover additional tissues.

43. Three comments stated that all tissue banks, despite their type, should be federally registered and subject to inspection and accreditation. One additional comment urged FDA to consider the use of a nongovernmental organization as a private accrediting and/or inspecting entity.

FDA declines to adopt the suggestions made by these comments as they relate to registration and accreditation at this time, as they are outside the scope of the rule, but is considering addressing registration and accreditation in future rulemaking, at which time comments will be solicited. Tissue facilities that are regulated under the provisions of the

interim rule are subject to and will continue to be subject to Federal inspection under the final rule.

44. One comment suggested that tissue banks should bank and hold serum specimens from donors for 5 years beyond the expiration date of the human tissue allograft for additional testing that may become relevant to public health in the future.

The comment did not provide any demonstrable evidence that such a practice is necessary for the protection of the public health. In the absence of such evidence, FDA declines to add such a requirement. Complete and careful donor screening and testing in accordance with the provisions of the rule, as well as maintenance of records for the period specified in § 1270.33(h) should provide sufficient information to investigate possible transmission of infectious disease. FDA is willing to consider evidence that such a requirement is warranted.

45. One comment urged a requirement that records show the destination of all human tissue released for transplant.

FDA is requiring disposition records for human tissue (distribution for transplantation, use for nonclinical research, or destruction) but is not requiring tracking to the recipient at this time. FDA is considering requirements for the tracking of human tissue for inclusion in future rulemaking. FDA discussed the tracking of human tissue under a Federal regulatory scheme with members of the industry at both the March 1995 and June 1995 workshops described earlier. FDA notes that currently the voluntary standards of the American Association of Tissue Banks and the Eye Bank Association of America include the tracking of human tissue from the donor to the recipient, transplanting surgeon or institution.

46. Three comments requested FDA to consider developing requirements for discussing donor medical history with the Next of Kin or others who might sign the donation consent form.

FDA recognizes the requests for requiring a donor medical history interview, and the need for guidance in conducting the donor medical history interview for assurance that the donor did not participate in high risk behavior for hepatitis and HIV infection. The donor medical history interview is an integral part of the relevant medical records and is defined as such in the final rule. FDA is announcing the availability of ''Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation'' elsewhere in this **Federal Register** to assist those facilities involved in determining the suitability of a donor.

47. Two comments inquired about the mechanism used by FDA in requiring new tests in the future and deleting obsolete tests, and added that a careful evaluation and decision analysis should consider the test's specificity, sensitivity, and positive utility.

It is the practice of FDA to thoroughly evaluate all data including that accumulated by its scientists, by industry scientists, and by academicians when considering the use of a test or deletion of a test for communicable disease. When appropriate, FDA presents such data to an advisory committee composed of specialists and requests their recommendation. Therefore, FDA evaluates the need to add or delete a test for communicable disease taking into account the available scientific data and the effect of the test on the public health.

48. One comment inquired as to the suitability of an umbilical cord blood specimen or the mother's blood specimen for viral marker testing on newborn donors.

To date, none of the viral marker test kits address cord blood as an adequate sample in the package insert. Cord blood may not be acceptable for testing if contamination of the specimen with Wharton's jelly occurs during collection. If an adequate cord blood specimen is not available, then the mother's blood specimen will be considered acceptable for testing. FDA has added § 1270.21(b) to the final rule to clarify that in the case of a neonate, the mother's specimen is acceptable for testing.

F. Comments on New Regulatory Areas

49. Forty-four comments were also received that were beyond the scope of this rulemaking. For example, five comments expressed concern that FDA would require user fees to fund the regulation of human tissue.

This final rule does not impose a user fee requirement for human tissue. User fee authority to fund tissue banking regulation was presented in legislation introduced by Representative Wyden in H.R. 3547 and Senator Simon in S. 1702 during the 1994 Congressional term. Neither bill was passed.

50. One comment stated that it would be appropriate to include recordkeeping and tracking requirements for hospitals and other transplant facilities.

FDA at this time declines to incorporate tracking requirements in this rule. Promulgation of tracking requirements would affect transplant facilities currently not within the scope of the final rule, unless they are involved in recovery, screening, testing, processing, or distribution of human tissue. In this rulemaking, FDA is not expanding the recordkeeping requirements beyond those in § 1270.35(c), or otherwise revising significantly its regulatory program on human tissue at this time. The comments are being considered as FDA reviews the possibility of further developing its regulatory program and may be the subject of future rulemaking.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The agency has also determined that this rule is a significant regulatory action under paragraph (f)(4) of the Executive Order because it raises novel policy issues.

The Regulatory Flexibility Act requires agencies to prepare a Regulatory Flexibility Analysis for each rule unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained below, the agency certifies that this rule will not have a significant impact on a substantial number of small entities.

A. The Need For the Regulation

The purpose of the final rule is to provide clarification of the interim rule, revise the rule in response to public comments, and finalize its provisions. The interim rule was promulgated as an emergency measure to protect the public safety against human tissue that had incomplete or no documentation ascertaining its freedom from communicable diseases. This risk was clearly demonstrated by evidence of human tissue from foreign sources that had been offered for sale in the United States with little documentation of appropriate screening and testing. The final rule takes into account comments submitted to the Dockets Management Branch, and discussions and information obtained through public participation in three workshops held following the promulgation of the interim rule. The objective of the final rule is to impose minimal requirements for testing and screening of human

tissue donors, while making all human tissue, imported and domestic, safe for transplant needs.

B. A Description of Requirements

The interim rule requires all facilities to ensure that specified minimum required medical screening and infectious disease testing has been performed and that records documenting such screening and testing for each human tissue are available for inspection by FDA. The final rule clarifies and modifies requirements in the interim rule and adds three additional requirements, which are currently voluntary industry standards: written procedures for the designation and identification of quarantined tissue (§ 1270.31(c)); written and validated procedures for the prevention of contamination or cross-contamination of tissues during processing (§ 1270.31(d)); and documentation of receipt and/or distribution of human tissue determined to be suitable for transplantation until it is distributed to the transplanting facility (section 1270.35(c)).

C. The Type and Number of Firms Affected

The rule will affect any establishment or person engaged in the recovery, screening, testing, processing, storage or distribution of human tissues. Because of their small size, tissue specialty, and/or interrelationship with other tissue establishments, most tissue establishments do not perform all of these activities. Thus, the effect of this rule will vary depending on the number and type of functions performed. Because tissue establishments are not currently required to register with FDA, the agency does not have a precise count of the number of establishments that will be affected by this rule. EBAA reports 110 member eye banks. Also, an FDA/HRSA sponsored survey projected that in 1994, about 67 tissue banks procured musculoskeletal tissue from cadaveric donors. (Jeffrey Prottas, (1995) ''A Study of the Tissue Procurement and Distribution System of the United States''). This survey also projected an additional 120 surgical bone banks, entities which typically involved one or more surgeons who save and freeze for later use bone obtained during routine surgical procedures. There also may exist an unknown number of uncounted skin banks. (Neither of these latter two groups—surgical bone and skin banks—are believed to account for substantial volume of tissue.) All together, therefore, FDA estimates that the rule may affect a total of about 400 establishments. Since the majority of these establishments employ fewer than 15 employees, the Small Business Administration would define almost all as small entities.

D. Nature of Impact

FDA finds that the final rule will have little adverse impact on the tissue industry. When issuing the interim rule, FDA took voluntary industry standards and State requirements into account to minimize the impact on the supply of tissue available for transplantation and to reduce the economic burden to industry. In its preamble to the interim regulation (58 FR 65519), FDA determined that the only economic impact of the rule would be related to the recordkeeping burdens, ''because the cost of testing for infectious disease and the cost of screening donors has already been assumed by the tissue banking industry and this interim rule imposes no additional burdens.'' The agency has received no new industry comment that would alter its conclusion that donor testing and screening are universally accepted practice for the industry.

The eye bank sector, however, has questioned the need for the potential burden associated with certain aspects of the interim donor screening requirements. Several comments suggested that the agency exempt corneas from regulations due to an adequate safety record and adequate internal standards (Comment 3). Some asked that the agency exempt these operations from the requirement for a donor medical history interview as part of the relevant medical record, if the document was not available; stating that this requirement makes it more difficult to procure corneas under legislative consent (Comment 27).

FDA has given great consideration to the impact that such changes would have on both the tissue establishments and the public health. The agency believes that all human tissues have the potential to transmit communicable diseases and that every reasonable effort should be made to prevent disease transmission, while ensuring the continued availability of safe human tissue. Keeping these elements in focus, FDA decided to regulate all human tissue under the same standards (protecting the public health by preventing disease transmission), while permitting the procurement of corneas under legislative consent when a donor medical history interview is not available. Thus, the final FDA rule allows greater flexibility in the procurement of corneal tissue under legislative consent, while minimizing any potential regulatory burden.

Similarly, the new requirements of the final rule, (e.g., preparing two standard operating procedures and increased documentation for receipt and/or distribution of human tissue) will not add significantly to operating costs. The final requirements are part of industry voluntary standards and therefore, are currently in place in most tissue banks. The 60 tissue banks and 110 eye banks that are currently members of the AATB and the EBAA, respectively, are likely to account for the great majority of tissue transactions. For those few establishments that do not have or must modify their existing written procedures, FDA estimates that they will require a one-time expenditure of approximately 7 hours for each of four required written SOP's. Furthermore, since the smaller tissue banks would be unlikely to process tissue (the Prottas survey projects that only 28 percent of the 67 musculoskeletal banks process tissue), the smaller tissue banks will need to prepare only three written procedures.

Likewise, the new requirements for documenting the distribution and receipt of human tissue will impose few costs. Prottas found that 95 percent of the surveyed musculoskeletal banks could track tissue to recipient institutions. These banks presumably already identify and document their products. Although the smallest tissue banks may need to expand this effort, the associated cost would be mitigated by the smaller number of transactions at such establishments.

In sum, the final rule sets minimal requirements to prevent the transmission of communicable diseases from human tissue used for transplantation. The vast majority of tissue establishments were voluntarily complying with most of the requirements of the interim rule before it was issued, and are voluntarily complying with the new requirements in this final rule. As described in Section V of this document, some entities may need to prepare or modify existing documentation procedures, but FDA believes that very few will need to alter actual operations. At almost no establishment would additional reporting and recordkeeping activities take over 20 hours of time annually for a nurse, physician assistant, or certified technician. As a result, FDA expects that very few entities will incur significant costs due to this rule. FDA therefore certifies that this rule will not have a significant impact on a substantial number of small entities.

V. Paperwork Reduction Act of 1995

Although the December 14, 1993, interim rule (58 FR 65514) provided a 90-day comment period under the Paperwork Reduction Act of 1980, and this final rule responds to the comments received, FDA is providing an additional opportunity for public comment under the Paperwork Reduction Act of 1995, which was enacted after the expiration of the comment period and applies to this final rule. Therefore, FDA now invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Individuals and organizations may submit comments on the information collection provisions of this final rule by September 29, 1997. Comments should be directed to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review and approval. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This final rule contains information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The title, description, and respondents of the information collections are shown below with an estimate of the annual recordkeeping and periodic reporting burden.

Title: Human Tissue Intended for Transplantation: 21 CFR part 1270.

Description: FDA is issuing final regulations to prevent the transmission of HIV, hepatitis B, and hepatitis C through the use of human tissue for transplantation. The final regulations closely parallel those contained in the interim rule on human tissue intended for transplantation. Both the interim and final rule provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet standards intended to ensure appropriate screening and testing of human tissue donors and ensure that records are kept documenting that the appropriate screening and testing have been completed.

Description of Respondents: Businesses or other for-profit; nonprofit institutions; small businesses or organizations.

There are approximately 60 tissue establishments with 300 employees that are members of the American Association of Tissue Banks. There are an additional 600 individual members of which 50 percent are performing a tissue banking activity. The Eye Bank Association of America's membership consists of 120 eye banks of which 110 are in the continental United States.

With the rare exceptions noted in the preamble, FDA believes that all respondents perform donor testing and screening for HIV and hepatitis and these regulations add no additional requirements. New § 1270.31(c) and (d) require written procedures for the designation and identification of quarantined tissue and to prevent the contamination or cross-contamination of tissue during processing. Section 1270.35(c) requires documentation of the distribution and receipt of human tissue, completing the accounting of tissue between determination of suitability, and the destruction or disposition of the tissue.

When the interim rule was promulgated, accredited members of the American Association of Tissue Banks and the Eye Bank Association of America were already in compliance with the regulations by adhering to the standards established by these organizations. The requirements added to the Final Rule will not impose additional burden since the members will be complying with the current organizations' standards which are comparable to the requirements in the final rule. To account for persons or establishments that may not be a member of an industry organization and, for whom therefore, the extent of compliance with the requirements of the final rule is unknown, FDA will be using 1 percent as an estimation of the information collection burden on the tissue industry.

Industry estimates that in 1994 there were 350,000 bone transplants, 42,000 corneal transplants, 5,000 patellar tendon transplants, and the transplantation of 5,000 square feet of skin. There are approximately 300 persons and 170 tissue banks currently operating in the United States affected by the regulations.

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1270.31(a) and 1270.31(b) and 1270.31(c) and 1270.31(d)	11	4	44	28	308
1270.35(a) and 1270.35(b)	11	420	4,620	290	3,190
1270.35(c)	11	2,893	31,823	4,782	52,602
1270.35(d)	11	17	187	17	187
Total					56,287

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1270

Communicable diseases, HIV/AIDS, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16 and 1270 are amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 28 U.S.C. 2112.

2. Section 16.1 is amended in paragraph (b)(2) by revising the entry for ''§ 1270.15(e) * * *'' to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1270.15(e), relating to the retention, recall, and destruction of human tissue.

3. Part 1270 is revised to read as follows:

PART 1270—HUMAN TISSUE INTENDED FOR TRANSPLANTATION

Subpart A—General Provisions

Sec.

Subpart B—Donor Screening and Testing

Subpart C—Procedures and Records

Subpart D—Inspection of Tissue Establishments

Authority: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

Subpart A—General Provisions

§ 1270.1 Scope.

(a) The regulations in this part apply to human tissue and to establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue.

(b) Regulations in this chapter as they apply to drugs, biologics, devices, or other FDA-regulated commodities do not apply to human tissue, except as specified in this part.

(c) Regulations in this chapter do not apply to autologous human tissue.

(d) Regulations in this chapter do not apply to hospitals or other clinical facilities that receive and store human tissue only for transplantation within the same facility.

§ 1270.3 Definitions.

(a) *Act* for the purpose of this part means the Public Health Service Act, section 361 (42 U.S.C. 264).

(b) *Blood component* means any part of a single-donor unit of blood separated by physical or mechanical means.

(c) *Colloid* means a protein or polysaccharide solution that can be used to increase or maintain osmotic (oncotic) pressure in the intravascular compartment such as albumin, dextran, hetastarch; or certain blood components, such as plasma and platelets.

(d) *Contract services* are those functions pertaining to the recovery, screening, testing, processing, storage, or distribution of human tissue that another establishment agrees to perform for a tissue establishment.

(e) *Crystalloid* means a balanced salt and/or glucose solution used for electrolyte replacement or to increase intravascular volume such as saline, Ringer's lactate solution, or 5 percent dextrose in water.

(f) *Distribution* includes any transfer or shipment of human tissue (including importation or exportation), whether or not such transfer or shipment is entirely intrastate and whether or not possession of the tissue is taken.

(g) *Donor* means a human being, living or dead, who is the source of tissue for transplantation.

(h) *Donor medical history interview* means a documented dialogue with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior; such as the donor if living, the next of kin, the nearest available relative, a member of the donor's household, other individual with an affinity relationship, and/or the primary treating physician. The relevant social history includes questions to elicit whether or not the donor met certain descriptions or engaged in certain activities or behaviors considered to place such an individual at increased risk for HIV and hepatitis.

(i) *Establishment* means any facility under one management including all locations, that engages in the recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation.

(j) *Human tissue* means any tissue derived from a human body, which:

(1) Is intended for transplantation to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease;

(2) Is recovered, processed, stored, or distributed by methods that do not change tissue function or characteristics;

(3) Is not currently regulated as a human drug, biological product, or medical device;

(4) Excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ; and

(5) Excludes semen or other reproductive tissue, human milk, and bone marrow.

(k) *Importer of record* means the person, establishment or their representative responsible for making entry of imported goods in accordance with all laws affecting such importation.

(l) *Legislative consent* means relating to any of the laws of the various States that allow the medical examiner or coroner to procure corneal tissue in the absence of consent of the donor's next-of-kin.

(m) *Person* includes an individual, partnership, corporation, association, or other legal entity.

(n) *Physical assessment* means a limited autopsy or recent antemortem or postmortem physical examination of the donor to assess for any signs of HIV and hepatitis infection or signs suggestive of any risk factor for such infections.

(o) *Plasma dilution* means a decrease in the concentration of the donor's plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids.

(p) *Processing* means any activity performed on tissue, other than tissue recovery, including preparation, preservation for storage, and/or removal from storage to assure the quality and/or sterility of human tissue. Processing includes steps to inactivate and remove adventitious agents.

(q) *Quarantine* means the identification of human tissue as not suitable for transplantation, including human tissue that has not yet been characterized as being suitable for

transplantation. Quarantine includes the storage of such tissue in an area clearly identified for such use, or other procedures, such as automated designation, for prevention of release of such tissue for transplantation.

(r) *Reconstituted blood* means the extracorporeal resuspension of a blood unit labeled as ''Red Blood Cells'' by the addition of colloids and/or crystalloids to produce a hematocrit in the normal range.

(s) *Recovery* means the obtaining from a donor of tissue that is intended for use in human transplantation.

(t) *Relevant medical records* means a collection of documents including a donor medical history interview, a physical assessment of the donor, laboratory test results, medical records, existing coroner and autopsy reports, or information obtained from any source or records which may pertain to donor suitability regarding high risk behaviors, clinical signs and symptoms for HIV and hepatitis, and treatments related to medical conditions suggestive of such risk.

(u) *Responsible person* means a person who is authorized to perform designated functions for which he or she is trained and qualified.

(v) *Storage* means holding tissue.

(w) *Summary of records* means a condensed version of the required testing and screening records that contains the identity of the testing laboratory, the listing and interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of the human tissue for transplantation.

(x) *Vascularized* means containing the original blood vessels which are intended to carry blood after transplantation.

Subpart B—Donor Screening and Testing

§ 1270.21 Determination of donor suitability for human tissue intended for transplantation.

(a) Donor specimens shall be tested for the following communicable viruses, using Food and Drug Administration (FDA) licensed donor screening tests in accordance with manufacturers' instructions:

(1) Human immunodeficiency virus, Type 1 (e.g., FDA licensed screening test for anti-HIV-1);

(2) Human immunodeficiency virus, Type 2 (e.g., FDA licensed screening test for anti-HIV-2);

(3) Hepatitis B (e.g., FDA licensed screening test for HBsAg); and

(4) Hepatitis C (e.g., FDA licensed screening test for anti-HCV).

(b) In the case of a neonate, the mother's specimen is acceptable for testing.

(c) Such infectious disease testing shall be performed by a laboratory certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA).

(d) Human tissue shall be accompanied by records indicating that the donor's specimen has been tested and found negative using FDA licensed screening tests for HIV–1, HIV–2, hepatitis B, and hepatitis C. FDA licensed screening tests labeled for cadaveric specimens must be used when available.

(e) Human tissue for transplantation shall be accompanied by a summary of records or copies of the original records of the donor's relevant medical records as defined in § 1270.3(t) which documents freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, or HIV infection. There shall be a responsible person designated and identified in the original record and summary of records as having made the determination that the human tissue is suitable for transplantation.

(f) Determination by the responsible person that a donor of human tissue intended for transplantation is suitable shall include ascertainment of the donor's identity, and accurately recorded relevant medical records (as defined in § 1270.3(t)) which documents freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, and HIV infection.

(g) For corneal tissue procured under legislative consent where a donor medical history screening interview has not occurred, a physical assessment of the donor is required and other available information shall be reviewed. The corneal tissue shall be accompanied by the summary of records documenting that the corneal tissue was determined to be suitable for transplantation in the absence of the donor medical history interview. Corneal tissue procured under legislative consent shall be documented as such in the summary of records.

(h) Human tissue shall be determined to be not suitable for transplantation if from:

(1) A donor whose specimen has tested repeatedly reactive on a screening test for HIV, hepatitis B, or hepatitis C;

(2) A donor where blood loss is known or suspected to have occurred and transfusion/infusion of more than 2,000 milliliters (mL) of blood (i.e., whole blood, reconstituted blood, or red blood cells), or colloids within 48 hours; or more than 2,000 mL of crystalloids within 1 hour; or any combination thereof prior to the collection of a blood specimen from the tissue donor for testing, unless:

(i) A pretransfusion or preinfusion blood specimen from the tissue donor is available for infectious disease testing; or

(ii) An algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to ensure that there has not been plasma dilution sufficient to affect test results; or

(3) A donor who is 12 years of age or less and has been transfused or infused at all, unless:

(i) A pretransfusion or preinfusion blood specimen from the tissue donor is available for infectious disease testing; or

(ii) An algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to ensure that there has not been plasma dilution sufficient to affect test results.

Subpart C—Procedures and Records

§ 1270.31 Written procedures.

(a) There shall be written procedures prepared and followed for all significant steps in the infectious disease testing process under § 1270.21 which shall conform to the manufacturers' instructions for use contained in the package inserts for the required tests. These procedures shall be readily available to the personnel in the area where the procedures are performed unless impractical. Any deviation from the written procedures shall be recorded and justified.

(b) There shall be written procedures prepared and followed for all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor as provided in § 1270.21. Such procedures shall be readily available to personnel who may perform the procedures. Any deviation from the written procedures shall be recorded and justified.

(c) There shall be written procedures prepared and followed for designating and identifying quarantined tissue.

(d) There shall be written procedures prepared, validated, and followed for prevention of infectious disease contamination or cross-contamination by tissue during processing.

(e) In conformity with this section, any facility may use current standard written procedures such as those in a technical manual prepared by another organization, provided the procedures

are consistent with and at least as stringent as the requirements of this part.

§ 1270.33 Records, general requirements.

(a) Records shall be maintained concurrently with the performance of each significant step required in this part in the performance of infectious disease screening and testing of donors of human tissue. All records shall be accurate, indelible, and legible. The records shall identify the person performing the work, the dates of the various entries, and shall be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular tissue involved.

(b) All human tissue shall be quarantined until the following criteria for donor suitability are satisfied:

(1) All infectious disease testing under § 1270.21 has been completed, reviewed by the responsible person, and found to be negative; or

(2) Donor screening has been completed, reviewed by the responsible person, and determined to assure freedom from risk factors for and clinical evidence of HIV infection, hepatitis B, and hepatitis C.

(c) All human tissue processed or shipped prior to determination of donor suitability must be under quarantine, accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation.

(d) All human tissue determined to be suitable for transplantation must be accompanied by a summary of records, or copies of such original records, documenting that all infectious disease testing and screening under § 1270.21 has been completed, reviewed by the responsible person, and found to be negative, and that the tissue has been determined to be suitable for transplantation.

(e) Human tissue shall be quarantined until the tissue is either determined to be suitable for transplantation or appropriate disposition is accomplished.

(f) All persons or establishments that generate records used in determining the suitability of the donor shall retain such records and make them available for authorized inspection or upon request by FDA. The person(s) or establishment(s) making the determination regarding the suitability of the donor shall retain all records, or true copies of such records required under § 1270.21, including all testing and screening records, and shall make them available for authorized inspection or upon request from FDA. Records that can be retrieved from another location by electronic means meet the requirements of this paragraph.

(g) Records required under this part may be retained electronically, or as original paper records, or as true copies such as photocopies, microfiche, or microfilm, in which case suitable reader and photocopying equipment shall be readily available.

(h) Records shall be retained at least 10 years beyond the date of transplantation if known, distribution, disposition, or expiration, of the tissue, whichever is latest.

§ 1270.35 Specific records.

Records shall be maintained that include, but are not limited to:

(a) Documentation of results and interpretation of all required infectious disease tests;

(b) Information on the identity and relevant medical records of the donor, as required by § 1270.21(e) in English or, if in another language translated to English and accompanied by a statement of authenticity by the translator which specifically identifies the translated document;

(c) Documentation of the receipt and/or distribution of human tissue; and

(d) Documentation of the destruction or other disposition of human tissue.

Subpart D—Inspection of Tissue Establishments

§ 1270.41 Inspections.

(a) An establishment covered by these regulations in this part, including any location performing contract services, shall permit an authorized inspector of the Food and Drug Administration (FDA) to make at any reasonable time and in a reasonable manner such inspection of the establishment, its facilities, equipment, processes, products, and records as may be necessary to determine compliance with the provisions of this part. Such inspections may be made with or without notice and will ordinarily be made during regular business hours.

(b) The frequency of inspection will be at the agency's discretion.

(c) The inspector shall call upon a responsible person of the establishment and may question the personnel of the establishment as the inspector deems necessary.

(d) The inspector may review and copy any records required to be kept pursuant to part 1270.

(e) The public disclosure of records containing the name or other positive identification of donors or recipients of human tissue will be handled in accordance with FDA's procedures on disclosure of information as set forth in 21 CFR part 20 of this chapter.

§ 1270.42 Human tissue offered for import.

(a) When human tissue is offered for entry, the importer of record must notify the director of the district of the Food and Drug Administration having jurisdiction over the port of entry through which the tissue is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part.

(b) Human tissue offered for import must be quarantined until the human tissue is released by FDA.

§ 1270.43 Retention, recall, and destruction of human tissue.

(a) Upon a finding that human tissue may be in violation of the regulations in this part, an authorized Food and Drug Administration (FDA) representative may:

(1) Serve upon the person who distributed the tissue a written order that the tissue be recalled and/or destroyed, as appropriate, and upon persons in possession of the tissue that the tissue shall be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or the safety of the tissue is confirmed; and/or

(2) Take possession of and/or destroy the violative tissue.

(b) The written order will ordinarily provide that the human tissue be recalled and/or destroyed within 5 working days from the date of receipt of the order and will state with particularity the facts that justify the order.

(c) After receipt of an order under this part, the person in possession of the human tissue shall not distribute or dispose of the tissue in any manner except to recall and/or destroy the tissue consistent with the provisions of the order, under the supervision of an authorized official of FDA.

(d) In lieu of paragraphs (b) and (c) of this section, other arrangements for assuring the proper disposition of the tissue may be agreed upon by the person receiving the written order and an authorized official of FDA. Such arrangements may include providing FDA with records or other written information that adequately assure that the tissue has been recovered, screened, tested, processed, stored, and distributed in conformance with part 1270.

(e) Within 5 working days of receipt of a written order for retention, recall, and/or destruction of tissue (or within 5 working days of the agency's possession

of such tissue), the recipient of the written order or prior possessor of such tissue shall request a hearing on the matter in accordance with part 16 of this chapter. The order for destruction will be held in abeyance pending resolution of the hearing request.

Dated: July 7, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 97–19819 Filed 7–28–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 88N–0320]

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls; Partial Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is announcing a continuation of the partial extension of the compliance date for a provision of the final rule, published in the **Federal Register** of August 3, 1993 (58 FR 41348), revising the packaging and labeling control provisions of the current good manufacturing practice (CGMP) regulations for the use of cut labeling. FDA is extending the date for compliance with a specific provision, as it applies to labeling other than immediate container labels, until the effective date of the regulation finalizing the proposed rule on this subject published elsewhere in this issue of the **Federal Register**.

DATES: The date for compliance with the cut labeling provision at § 211.122(g) (21 CFR 211.122(g)), as it applies to labeling other than immediate container labels, is extended until the effective date of the regulation finalizing the proposed rule on this subject published elsewhere in this issue of the **Federal Register**. The date for compliance with all other provisions of the August 3, 1993, final rule remains August 3, 1994.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5621 (Internet electronic mail: kuchenbergt@cder.fda.gov), or Paul J. Motise, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1089 (Internet electronic mail: motise@cder.fda.gov).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 3, 1993 (58 FR 41348), FDA published a final rule amending the current good manufacturing practice (CGMP) regulations to require that special control procedures be instituted if cut labeling is used in packaging and labeling operations. One of these procedures requires the use of ''appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations'' (§ 211.122(g)(2)). The rule applied to all types of labeling, including product inserts, multiunit containers packaged in individual containers, and shipping containers.

In May 1994, FDA received two citizen petitions from several trade associations requesting that the agency extend the effective date of the rule and reopen the administrative record to receive additional comments on the application of § 211.122(g) to items of labeling other than the immediate container label. The petitions stated that additional time was needed to obtain, install, or validate equipment necessary to comply with the rule. The citizen petitions also asserted that the final rule inappropriately expanded the scope of § 211.122(g) from immediate container labels to all drug product labeling.

In the **Federal Register** of August 2, 1994 (59 FR 39255), FDA extended the compliance date for § 211.122(g) as it applies to labeling other than immediate container labels, and opened the administrative record through October 4, 1994, for comments on the scope of § 211.122(g). All other provisions of the final rule became effective on August 3, 1994. FDA further extended the compliance date to August 2, 1996, in the **Federal Register** of April 28, 1995 (60 FR 20897), and to August 1, 1997, in the **Federal Register** of July 19, 1996 (61 FR 37679).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would limit the scope of § 211.122(g) to immediate container labels, individual unit cartons, or multiunit cartons when immediate containers are not packaged in individual cartons. The proposed rule would also permit the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

In this final rule, FDA is extending the date for compliance with § 211.122(g), as it applies to labeling other than immediate container labels, until the effective date of the regulation finalizing the proposed rule on this subject published elsewhere in this issue of the **Federal Register**. The date for compliance with all other provisions of the August 3, 1993, final rule remains August 3, 1994.

Dated: July 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–19818 Filed 7–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8726]

RIN 1545–AT95

Requirements for Tax Exempt Section 501(c)(5) Organizations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations clarifying certain requirements of section 501(c)(5). The requirements are clarified to provide needed guidance to organizations on the requirements an organization must meet in order to be exempt from tax as an organization described in section 501(c)(5).

DATES: These regulations are effective on December 21, 1995.

FOR FURTHER INFORMATION CONTACT: Robin Ehrenberg, (202) 622–6080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 21, 1995, the IRS published in the **Federal Register** (60 FR 66228) a notice of proposed rulemaking under section 501(c)(5). The proposed regulations clarified that organizations whose principal activity is administering retirement plans are not section 501(c)(5) organizations.

A public hearing was held on June 5, 1996. Written comments were received. After consideration of all of the comments, the proposed regulations under section 501(c)(5) are adopted as revised by this Treasury Decision. The comments and revisions are discussed below.

Explanation of Revisions and Summary of Comments

Section 501(c)(5) describes certain labor, agricultural and horticultural organizations. Section 401(a) sets forth the requirements for exemption for qualified employee benefit pension trusts. Section 501(a) exempts from federal income taxes organizations described in section 401(a) or section 501(c). Thus, section 401(a) and section 501(c)(5) should be read as enactments of Congress *in pari materia,* taken together as one consistent body of law. *Pacific Co.* v. *Johnson,* 285 U.S. 480, 495 (1932).

The Treasury and IRS believe that section 501(c)(5) should be interpreted in a manner consistent with the Employee Retirement Income Security Act of 1974, Pub. L. No. 93–406, 88 Stat. 829 (1974) (ERISA), as amended. ERISA was enacted as a ''comprehensive and reticulated statute'' to regulate retirement plans and trusts, ''the product of a decade of Congressional study of the Nation's private employee benefit system.'' *Mertens* versus *Hewitt Assoc.*, 508 U.S. 248, 251 (1993), citing *Nachman* versus *PBGC,* 46 U.S. 359, 361 (1980). Congress intended that pension trusts satisfy the comprehensive requirements of section 401(a), as amended by ERISA, in order to be tax exempt. See S. Rep. No. 383, 93d Cong., 1st Sess. at 33, reprinted in 1974–3 C.B. (Supp.) 112; H. Rep. No. 807, 93d Cong., 1st Sess. at 33, reprinted in 1974–3 C.B. (Supp.) 236, 266.

Accordingly, Treasury and the IRS continue to believe that an organization whose principal purpose is managing employer-sponsored retirement plans is not an exempt labor organization described in section 501(c)(5). (However, an employer-sponsored pension trust may nevertheless qualify for exemption under section 501(a) if it meets the requirements of section 401(a).) *Morganbesser* versus *United States,* 984 F.2d 560 (2d Cir. 1993), nonacq. 1995–2 C.B. 2.; In re Morganbesser, AOD CC–1995–016 (Dec. 26, 1995).

Consistent with ERISA and interpreting section 401(a) and section 501(c)(5) as part of a consistent whole, these regulations provide a general rule that an organization is not described in section 501(c)(5) if its principal activity is to receive, hold, invest, disburse or otherwise manage funds associated with savings or investment plans or programs, including pension or other retirement savings plans or programs. However, to the extent that ERISA provides special rules for certain types of retirement savings plans, it is appropriate to take those rules into account in interpreting provisions of the Code relating to such plans, including section 501(c)(5).

As noted by one commentator, ERISA excepts certain dues-financed plans from Parts 2 and 3 of Title I of ERISA (vesting, funding and certain other qualification requirements). Those pension trusts sponsored by labor organizations for their members, which accept no employer contributions, do not qualify for exemption under section 401(a) because they are not maintained by an employer. Section 401(a), Rev. Rul. 80–306, 1980–2 C.B. 131. Accordingly, the regulations provide that an organization (including a pension trust) may qualify as an organization described in section 501(c)(5) if it meets all of the following requirements:

(1) The organization is established and maintained by another labor organization described in section 501(c)(5) (determined without reference to the tests in Treas. Reg. § 1.501(c)(5)–1(b)(2));

(2) The organization is not directly or indirectly established or maintained in whole or in part by any employer or by any government (or any agency, instrumentality or controlled entity thereof);

(3) The organization is funded by membership dues paid to the labor organization establishing and maintaining the organization and earnings thereon; and

(4) After September 2, 1974 (the date of enactment of ERISA, 88 Stat. 829), the organization's governing documents have not permitted or provided for nor did the organization accept, any contribution from any employer or from any government (or any agency, instrumentality or controlled entity thereof). Treas. Reg. § 1.501(c)(5)–1(b)(2).

Treas. Reg. § 1.892–2T(c) governs the tax status of a pension trust that is wholly owned and controlled by a foreign sovereign.

Scope

These regulations solely address the tax exempt status of organizations under section 501(c)(5) whose principal activity is to receive, hold, invest, disburse, or otherwise manage funds associated with savings or investment plans or programs. Other Code sections and tax principles apply to the tax exempt status of these organizations and the tax consequences of these arrangements to employers and participants in these arrangements.

One commentator requested that the IRS clarify that the regulations do not apply to health and welfare benefits not specifically mentioned in the regulations, such as retiree health benefits, death benefits, and group legal services. The regulations address only savings or investment plans or programs, (including pension or other retirement savings plans or programs) and do not address other types of benefits. *Cf.* Rev. Rul. 62–17, 962–1 C.B. 87.

Special Analyses

It has been determined that this Treasury Decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the notice of proposed rulemaking preceding the regulations was issued prior to March 29, 1996, the Regulatory Flexibility Act, (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Robin Ehrenberg, Office of Associate Chief Counsel (Employee Benefits and Exempt Organizations). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.501(c)(5)–1 is amended by:

1. Redesignating paragraph (b) as paragraph (c).

2. Adding a new paragraph (b).

The addition reads as follows:

§ 1.501(c)(5)–1 Labor, agricultural, and horticultural organizations.

* * * * *

(b)(1) *General rule.* An organization is not an organization described in section 501(c)(5) if the principal activity of the organization is to receive, hold, invest, disburse or otherwise manage funds associated with savings or investment plans or programs, including pension or other retirement savings plans or programs.

(2) *Exception.* Paragraph (b)(1) of this section shall not apply to an organization which—

(i) Is established and maintained by another labor organization described in section 501(c)(5) (determined without regard to this paragraph (b)(2));

(ii) Is not directly or indirectly established or maintained in whole or in part by one or more—

(A) Employers;

(B) Governments or agencies or instrumentalities thereof; or

(C) Government controlled entities;

(iii) Is funded by membership dues from members of the labor organization described in this paragraph (b)(2) and earnings thereon; and

(iv) Has not at any time after September 2, 1974 (the date of enactment of the Employee Retirement Income Security Act of 1974, Pub. L. 93–406, 88 Stat. 829) provided for, permitted or accepted employer contributions.

(3) *Example.* The principles of this paragraph (b) are illustrated by the following example:

Example. Trust A is organized in accordance with a collective bargaining agreement between labor union K and multiple employers. Trust A forms part of a plan that is established and maintained pursuant to the agreement and which covers employees of the signatory employers who are members of K. Representatives of both the employers and K serve as trustees. A receives contributions from the employers who are subject to the agreement. Retirement benefits paid to K's members as specified in the agreement are funded exclusively by the employers' contributions and accumulated earnings. A also provides information to union members about their retirement benefits and assists them with administrative tasks associated with the benefits. Most of A's activities are devoted to these functions. From time to time, A also participates in the renegotiation of the collective bargaining agreement. A's principal activity is to receive, hold, invest, disburse, or otherwise manage funds associated with a retirement savings plan. In addition, A does not satisfy all the requirements of the exception described in paragraph (b)(2) of this section. (For example, A accepts contributions from employers.) Therefore, A is not a labor organization described in section 501(c)(5).

* * * * *

Michael P. Dolan,

Acting Commissioner of Internal Revenue.

Approved: July 8, 1997.

Donald C. Lubick,

Acting Assistant Secretary of the Treasury.

[FR Doc. 97–19814 Filed 7–28–97; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (Admiralty) of the Navy has determined that USS PEARL HARBOR (LSD 52) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval vessel. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: June 26, 1997.

FOR FURTHER INFORMATION CONTACT: Captain R. R. Pixa, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, Virginia, 22332–2400, Telephone Number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Deputy Assistant Judge Advocate General (Admiralty) of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS PEARL HARBOR (LSD 52) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS: Annex I, section 3(a), pertaining to the horizontal distance between the forward and after masthead lights, without interfering with its special function as a naval vessel. The Deputy Assistant Judge Advocate General (Admiralty) of the Navy has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

Accordingly, 32 CFR Part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR Part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

2. Table Five of § 706.2 is amended by adding, in numerical order, the following entry for the USS PEARL HARBOR:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *

TABLE FIVE

Vessel	No.	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than ½ ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained
* * * *		*	*		*
USS PEARL HARBOR	LSD 52			X	63.9
* * * *		*	*		*

Dated: June 26, 1997.

R.R. Pixa,

Captain, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty).

[FR Doc. 97–19831 Filed 7–28–97; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 2

[Docket No. 970410086–7174–02]

RIN 0651–AA92

Revision of Patent and Trademark Fees for Fiscal Year 1998

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office (PTO) is amending the rules of practice in patent and trademark cases to adjust certain patent fee and trademark service fee amounts to reflect fluctuations in the Consumer Price Index (CPI) and to recover costs of operation.

EFFECTIVE DATE: October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Matthew Lee by telephone at (703) 305–8051, fax at (703) 305–8007, or by mail marked to his attention and addressed to the Commissioner of Patents and Trademarks, Office of Finance, Crystal Park 1, Suite 802, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: This rule change is designed to adjust PTO fees in accordance with the applicable provisions of title 35, United States Code; section 31 of the Trademark (Lanham) Act of 1946 (15 U.S.C. 1113); and section 10101 of the Omnibus Budget Reconciliation Act of 1990 (as amended by section 8001 of Public Law 103–66), all as amended by the Patent and Trademark Office Authorization Act of 1991 (Pub. L. 102–204).

When the ''Revision of Patent and Trademark Fees for Fiscal Year 1998'' was published as a proposed rule, the PTO assumed that the fee revisions would not become effective until after the ''1996 Changes to Patent Practice and Procedure'' (hereinafter ''Miscellaneous Changes''). See 61 FR 49819 (Sept. 23, 1996) (proposed Miscellaneous Changes rule). The changes proposed in the fee revision notice of proposed rulemaking have been modified to take into account that the fee revision rule will become effective before the Miscellaneous Changes rulemaking.

Background

Statutory Provisions

Patent fees are authorized by 35 U.S.C. 41 and 35 U.S.C. 376. A fifty percent reduction in the fees paid under 35 U.S.C. 41 (a) and (b) by independent inventors, small business concerns, and nonprofit organizations who meet prescribed definitions is required by 35 U.S.C. 41(h).

Subsection 41(f) of title 35, United States Code, provides that fees established under 35 U.S.C. 41 (a) and (b) may be adjusted on October 1, 1992, and every year thereafter, to reflect fluctuations in the Consumer Price Index (CPI) over the previous twelve months.

Section 10101 of the Omnibus Budget Reconciliation Act of 1990 (amended by section 8001 of Public Law 103–66) provides that there shall be a surcharge on all fees established under 35 U.S.C. 41(a) and (b) to collect $119 million in fiscal year 1998.

Subsection 41(d) of title 35, United States Code, authorizes the Commissioner to establish fees for all other processing, services, or materials related to patents to recover the average cost of providing these services or materials, except for the fees for recording a document affecting title, for each photocopy, and for each black and white copy of a patent.

Section 376 of title 35, United States Code, authorizes the Commissioner to set fees for patent applications filed under the Patent Cooperation Treaty (PCT).

Subsection 41(g) of title 35, United States Code, provides that new fee amounts established by the Commissioner under section 41 may take effect thirty days after notice in the **Federal Register** and the Official Gazette of the Patent and Trademark Office.

Section 31 of the Trademark (Lanham) Act of 1946, as amended (15 U.S.C. 1113), authorizes the Commissioner to establish fees for the filing and processing of an application for the registration of a trademark or other mark, and for all other services and materials relating to trademarks and other marks.

Section 31(a) of the Trademark (Lanham) Act of 1946 (15 U.S.C. 1113(a)), as amended, allows trademark fees to be adjusted once each year to reflect, in the aggregate, any fluctuations during the preceding twelve months in the CPI.

Section 31 also allows new trademark fee amounts to take effect thirty days after notice in the **Federal Register** and the Official Gazette of the Patent and Trademark Office.

Recovery Level Determinations

This rule adjusts patent fee and trademark service fee amounts for a planned recovery of $763,391,000 in fiscal year 1998, as proposed in the Administration's budget request to the Congress.

The patent statutory fees established by 35 U.S.C. 41 (a) and (b) will be adjusted on October 1, 1997, to reflect any fluctuations occurring during the previous twelve months in the Consumer Price Index for all urban consumers (CPI–U). In calculating these

fluctuations, the Office of Management and Budget (OMB) has determined that the PTO should use CPI–U data as determined by the Secretary of Labor. However, the Department of Labor does not make public the CPI–U until approximately twenty-one days after the end of the month being calculated. Therefore, the latest CPI–U information available is for the month of June 1997. In accordance with previous rulemaking methodology, the PTO uses the Administration's projected CPI–U for the twelve-month period ending September 30, 1997, which is 2.6 percent. Based on this projection, patent statutory fees will be adjusted by 2.6 percent. Before the final fee schedule is published, the fees may be adjusted slightly based on updated data available from the Department of Labor.

Certain non-statutory patent processing fees established under 35 U.S.C. 41(d) and PCT processing fees established under 35 U.S.C. 376 will be adjusted to recover their estimated average costs in fiscal year 1998.

Three patent service fees that are set by statute will not be adjusted. The three fees that are not being adjusted are assignment recording fees, printed patent copy fees and photocopy charge fees.

Certain trademark service fees established under 15 U.S.C. 1113 will be adjusted to recover their estimated average costs in fiscal year 1998.

The fee amounts were rounded by applying standard arithmetic rules so that the amounts rounded would be convenient to the user. Fees of $100 or more were rounded to the nearest $10. Fees between $2 and $99 were rounded to an even number so that any comparable small entity fee would be a whole number.

Workload Projections

Determination of workload varies by fee. Principal workload projection techniques are as follows:

Patent application workloads are projected from statistical regression models using recent application filing trends. Patent issues are projected from an in-house patent production model and reflect examiner production achievements and goals. Patent maintenance fee workloads utilize patents issued 3.5, 7.5 and 11.5 years prior to payment and assume payment rates of 78 percent, 54 percent and 32 percent, respectively. Service fee workloads follow linear trends from prior years' activities.

General Procedures

Any fee amount that is paid on or after the effective date of the proposed fee increase would be subject to the new fees then in effect. For purposes of determining the amount of the fee to be paid, the date of mailing indicated on a proper Certificate of Mailing or Transmission, where authorized under 37 CFR 1.8, will be considered to be the date of receipt in the PTO. A Certificate of Mailing or Transmission under § 1.8 is not proper for items which are specifically excluded from the provisions of § 1.8. Section 1.8 should be consulted for those items for which a Certificate of Mailing or Transmission is not proper. Such items include, inter alia, the filing of national and international applications for patents and the filing of trademark applications. However, the provisions of 37 CFR 1.10 relating to filing papers and fees using the ''Express Mail'' service of the United States Postal Service (USPS) do apply to any paper or fee (including patent and trademark applications) to be filed in the PTO. If an application or fee is filed by ''Express Mail'' with a date of deposit with the USPS (shown by the ''date in'' on the ''Express Mail'' mailing label) which is dated on or after the effective date of the rules, as amended, the amount of the fee to be paid would be the fee established by the amended rules.

In order to ensure clarity in the implementation of the new fees, a discussion of specific sections is set forth below.

Discussion of Specific Rules

37 CFR 1.16 National Application Filing Fees

Section 1.16, paragraphs (a), (b), (d), and (f) through (i), is revised to adjust fees established therein to reflect fluctuations in the CPI.

37 CFR 1.17 Patent Application Processing Fees

Section 1.17, paragraphs (b) through (g), (m), (r) and (s), is revised to adjust fees established therein to reflect fluctuations in the CPI.

Section 1.17, paragraphs (j) and (n) through (p), is revised to adjust fees established therein to recover costs.

37 CFR 1.18 Patent Issue Fees

Section 1.18, paragraphs (a) through (c), is revised to adjust fees established therein to reflect fluctuations in the CPI.

37 CFR 1.19 Document Supply Fees

Section 1.19, paragraphs (a)(2) and (a)(3), is revised to adjust fees established therein to recover costs.

37 CFR 1.20 Post-Issuance Fees

Section 1.20, paragraphs (c), (i), and (j), is revised to adjust fees established therein to recover costs.

Section 1.20, paragraphs (e) through (g), is revised to adjust fees established therein to reflect fluctuations in the CPI.

37 CFR 1.21 Miscellaneous Fees and Charges

Section 1.21, paragraphs (a)(1)(ii), (a)(6) and (j), is revised to adjust fees established therein to recover costs.

37 CFR 1.445 International Application Filing, Processing, and Search Fees

Section 1.445, paragraph (a), is revised to adjust the fees authorized by 35 U.S.C. 376 to recover costs and reflect current business practices.

37 CFR 1.482 International Preliminary Examination Fees

Section 1.482, paragraphs (a)(1)(i), (a)(1)(ii), and (a)(2)(ii), is revised to adjust the fees authorized by 35 U.S.C. 376 to recover costs.

37 CFR 1.492 National Stage Fees

Section 1.492, paragraphs (a), (b) and (d), is revised to adjust fees established therein to reflect fluctuations in the CPI.

37 CFR 2.6 Trademark Fees

Section 2.6, paragraphs (b)(4) and (b)(10), is revised to adjust fees established therein to recover costs.

Response to Comments on the Rules

A notice of proposed rulemaking to adjust patent fee and trademark service fee amounts was published in the **Federal Register** on May 7, 1997, at 62 FR 24865 and in the Official Gazette of the United States Patent and Trademark Office on May 27, 1997, at 1198 OG 97.

Comment: A respondent stated that many of the elements comprising the U.S. Department of Labor's Consumer Price Index (CPI) have no effect on PTO's costs of operation. The respondent also stated that fee increases should reflect only that portion of the CPI affecting PTO's costs of operation.

Response: The PTO is required by law to base its inflationary fee increases on fluctuations in the CPI over the twelve months prior to the effective date of the fee increase. While it is true that some of the elements that constitute the CPI have no effect on the cost of operations of the PTO, the CPI itself has considerable impact on the PTO. Salary increases for Federal employees have increased at rates that closely match the CPI, and employee compensation alone accounts for over 55 percent of PTO's annual costs. The PTO, just like any

other public or private organization, must procure supplies, pay rent and utilities, and incur numerous other expenses in the course of operations. Unfortunately, these costs rarely decline with each passing year.

Comment: A respondent stated that the PTO should adjust fees that are less than $100 in increments of at least $5 to avoid having amounts which make the calculation of fees inconvenient to the users.

Response: In the Recovery Level Determinations section of this rule package, it states that ''Fees between $2 and $99 were rounded to an even number so that any comparable small entity fee would be a whole number.'' This rounding methodology enables the PTO to set large and small entity fee amounts which are convenient overall to the users.

Other Considerations

This rulemaking contains no information collection within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* This rule has been determined to be not significant for purposes of Executive Order 12866. The PTO has determined that this rule change has no Federalism implications affecting the relationship between the National Government and the States as outlined in Executive Order 12612.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that the rule change would not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The rule change increases fees to reflect the change in the CPI as authorized by 35 U.S.C. 41(f). Further, the principal impact of the major patent fees has already been taken into account in 35 U.S.C. 41(h), which provides small entities with a fifty percent reduction in the major patent fees.

A comparison of existing and new fee amounts is included as an Appendix to this final rule.

Lists of Subjects

37 CFR Part 1

Administrative practice and procedure, Inventions and patents, Reporting and record keeping requirements, Small businesses.

37 CFR Part 2

Administrative practice and procedure, Courts, Lawyers, Trademarks

For the reasons set forth in the preamble, the PTO is amending title 37 of the Code of Federal Regulations, Parts 1 and 2, as set forth below.

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 would continue to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.16 is amended by revising paragraphs (a), (b), (d), and (f) through (i) to read as follows:

§ 1.16 National application filing fees.

(a) Basic fee for filing each application for an original patent, except provisional, design or plant applications:
By a small entity (§ 1.9(f))....$395.00
By other than a small entity $790.00

(b) In addition to the basic filing fee in an original application, except provisional applications, for filing or later presentation of each independent claim in excess of 3:
By a small entity (§ 1.9(f))....$41.00
By other than a small entity $82.00

* * * * *

(d) In addition to the basic filing fee in an original application, except provisional applications, if the application contains, or is amended to contain, a multiple dependent claim(s), per application:
By a small entity (§ 1.9(f))....$135.00
By other than a small entity $270.00

* * * * *

(f) Basic fee for filing each design application:
By a small entity (§ 1.9(f))....$165.00
By other than a small entity $330.00

(g) Basic fee for filing each plant application, except provisional applications:
By a small entity (§ 1.9(f))....$270.00
By other than a small entity $540.00

(h) Basic fee for filing each reissue application:
By a small entity (§ 1.9(f))....$395.00
By other than a small entity $790.00

(i) In addition to the basic filing fee in a reissue application, for filing or later presentation of each independent claim which is in excess of the number of independent claims in the original patent:
By a small entity (§ 1.9(f))....$41.00
By other than a small entity $82.00

* * * * *

3. Section 1.17 is amended by revising paragraphs (b) through (g), (j), (m) through (p), (r), and (s) to read as follows:

§ 1.17 Patent application processing fees.

* * * * *

(b) Extension fee for response within second month pursuant to § 1.136(a):
By a small entity (§ 1.9(f))....$200.00
By other than a small entity $400.00

(c) Extension fee for response within third month pursuant to § 1.136(a):
By a small entity (§ 1.9(f))....$475.00
By other than a small entity $950.00

(d) Extension fee for response within fourth month pursuant to § 1.136(a):
By a small entity (§ 1.9(f))....$755.00
By other than a small entity $1,510.00

(e) For filing a notice of appeal from the examiner to the Board of Patent Appeals and Interferences:
By a small entity (§ 1.9(f))....$155.00
By other than a small entity $310.00

(f) In addition to the fee for filing a notice of appeal, for filing a brief in support of an appeal:
By a small entity (§ 1.9 (f))....$155.00
By other than a small entity $310.00

(g) For filing a request for an oral hearing before the Board of Patent Appeals and Interferences in an appeal under 35 U.S.C. 134:
By a small entity (§ 1.9(f))....$135.00
By other than a small entity $270.00

* * * * *

(j) For filing a petition to institute a public use proceeding under § 1.292 ....$1,510.00

* * * * *

(m) or filing a petition:

(1) For revival of an unintentionally abandoned application, or (2) For the unintentionally delayed payment of the fee for issuing a patent:
By a small entity (§ 1.9(f))....$660.00
By other than a small entity $1,320.00

(n) For requesting publication of a statutory invention registration prior to the mailing of the first examiner's action pursuant to § 1.104—$920.00 reduced by the amount of the application basic filing fee paid.

(o) For requesting publication of a statutory invention registration after the mailing of the first examiner's action pursuant to § 1.104—$1,840.00 reduced by the amount of the application basic filing fee paid.

(p) For submission of an information disclosure statement under § 1.97(c) $240.00

* * * * *

(r) For entry of a submission after final rejection under § 1.129(a):
By a small entity (§ 1.9(f))....$395.00
By other than a small entity $790.00

(s) For each additional invention requested to be examined under § 1.129(b):
By a small entity (§ 1.9(f))....$395.00
By other than a small entity $790.00

4. Section 1.18 is revised to read as follows:

§ 1.18 Patent issue fees.

(a) Issue fee for issuing each original or reissue patent, except a design or plant patent:
By a small entity (§ 1.9(f))....$660.00
By other than a small entity $1,320.00

(b) Issue fee for issuing a design patent:
By a small entity (§ 1.9(f))....$225.00
By other than a small entity $450.00

(c) Issue fee for issuing a plant patent:
By a small entity (§ 1.9(f))....$335.00
By other than a small entity $670.00

5. Section 1.19 is amended by revising paragraphs (a)(2) and (a)(3) to read as follows:

§ 1.19 Document supply fees.

(a) * * *

(2) Printed copy of a plant patent in

color $15.00
(3) Copy of a utility patent or statutory invention registration containing color drawing (see § 1.84(a)(2)).....$25.00
* * * * *

6. Section 1.20 is amended by revising paragraphs (c), (e) through (g), (i)(1), (i)(2), and (j)(1) through (j)(3) to read as follows:

§ 1.20 Post issuance fees.

* * * * *
(c) For filing a request for reexamination (§ 1.510(a)).....$2,520.00
* * * * *

(e) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond four years; the fee is due by three years and six months after the original grant:
By a small entity (§ 1.9(f)).....$525.00
By other than a small entity $1,050.00

(f) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond eight years; the fee is due by seven years and six months after the original grant:
By a small entity (§ 1.9(f)).....$1,050.00
By other than a small entity $2,100.00

(g) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond twelve years; the fee is due by eleven years and six months after the original grant:
By a small entity (§ 1.9(f)).....$1,580.00
By other than a small entity $3,160.00
* * * * *

(i) * * *
(1) Unavoidable.....$700.00
(2) Unintentional $1,640.00

(j) * * *
(1) Application for extension under § 1.740 .....$1,120.00
(2) Initial application for interim extension under § 1.790. .....$420.00
(3) Subsequent application for interim extension under § 1.790 .....$220.00

7. Section 1.21 is amended by revising paragraphs (a)(1)(ii), (a)(6) and (j) to read as follows:

§ 1.21 Miscellaneous fees and charges.

(a) * * *
(1) * * *
(ii) Registration examination fee $310.00
* * * * *

(6) For requesting regrading of an examination under § 10.7(c):
(i) Regrading of morning section (PTO Practice and Procedure) $230.00
(ii) Regrading of afternoon section (Claim Drafting) $540.00
* * * * *
(j) Labor charges for services, per hour or fraction thereof.....$40.00
* * * * *

8. Section 1.445 is amended by revising paragraph (a) to read as follows:

§ 1.445 International application filing, processing and search fees.

(a) The following fees and charges for international applications are established by the Commissioner under the authority of 35 U.S.C. 376:
(1) A transmittal fee (see 35 U.S.C. 361(d) and PCT Rule 14) $240.00
(2) A search fee (see 35 U.S.C. 361(d) and PCT Rule 16):
(i) Where a corresponding prior United States National application filed under 35 U.S.C. 111(a) with the filing fee under 37 CFR 1.16(a) has been filed $450.00
(ii) For all situations not provided for in (a)(2)(i) of this section $700.00
(3) A supplemental search fee when required, per additional invention $210.00
* * * * *

9. Section 1.482 is amended by revising paragraphs (a)(1)(i), (a)(1)(ii), and (a)(2)(ii) to read as follows:

§ 1.482 International preliminary examination fees.

(a) * * *
(1) * * *
(i) Where an international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office as an International Searching Authority, a preliminary examination fee of $490.00
(ii) Where the International Searching Authority for the international application was an authority other than the United States Patent and Trademark Office, a preliminary examination fee of $750.00
(2) * * *
(ii) Where the International Searching Authority for the international application was an authority other than the United States Patent and Trademark Office.....$270.00
* * * * *

10. Section 1.492 is amended by revising paragraphs (a), (b) and (d) to read as follows:

§ 1.492 National stage fees.

* * * * *
(a) The basic national fee:
(1) Where an international preliminary examination fee as set forth in § 1.482 has been paid on the international application to the United States Patent and Trademark Office:
By a small entity (§ 1.9(f)).....$360.00
By other than a small entity $720.00
(2) Where no international preliminary examination fee as set forth in § 1.482 has been paid to the United States Patent and Trademark Office, but an international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office as an International Searching Authority:
By a small entity (§ 1.9(f)).....$395.00
By other than a small entity $790.00
(3) Where no international preliminary examination fee as set forth in § 1.482 has been paid and no international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office:
By a small entity (§ 1.9(f)).....$535.00
By other than a small entity $1,070.00
(4) Where an international preliminary examination fee as set forth in § 1.482 has been paid to the United States Patent and Trademark Office and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness), and industrial applicability, as defined in PCT Article 33 (1) to (4) have been satisfied for all the claims presented in the application entering the national stage (see § 1.496(b)):
By a small entity (§ 1.9(f)).....$49.00
By other than a small entity $98.00
(5) Where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office:
By a small entity (§ 1.9(f)).....$465.00
By other than a small entity $930.00
(b) In addition to the basic national fee, for filing or later presentation of each independent claim in excess of 3:
By a small entity (§ 1.9(f)).....$41.00
By other than a small entity $82.00
* * * * *
(d) In addition to the basic national fee, if the application contains, or is amended to contain, a multiple dependent claim(s), per application:
By a small entity (§ 1.9(f)).....$135.00
By other than a small entity $270.00
* * * * *

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

1. The authority citation for 37 CFR Part 2 would continue to read as follows:

Authority: 15 U.S.C. 1123; 35 U.S.C. 6, unless otherwise noted.

2. Section 2.6 is amended by revising paragraphs (b)(4) and (b)(10) to read as follows:

§ 2.6 Trademark fees.

* * * * *
(b) Trademark service fees.
* * * * *
(4) Certified copy of a registered mark, showing title and/or status:
(i) Regular service $15.00
(ii) Expedited local service.....$30.00
* * * * *
(10) Labor charges for services, per hour or fraction thereof.....$40.00
* * * * *

Dated: July 22, 1997.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

Note—The following appendix is provided as a courtesy to the public, but is not a

substitute for the rules. It will not appear in the Code of Federal Regulations.

Appendix A—Comparison of Existing and Revised Fee Amounts

37 CFR Sec.	Description	Pre-Oct 1997	Oct 1997
1.16(a)	Basic Filing Fee	$770	$790
1.16(a)	Basic Filing Fee (Small Entity)	385	395
1.16(b)	Independent Claims	80	82
1.16(b)	Independent Claims (Small Entity)	40	41
1.16(c)	Claims in Excess of 20	22	—
1.16(c)	Claims in Excess of 20 (Small Entity)	11	—
1.16(d)	Multiple Dependent Claims	260	270
1.16(d)	Multiple Dependent Claims (Small Entity)	130	135
1.16(e)	Surcharge—Late Filing Fee	130	—
1.16(e)	Surcharge—Late Filing Fee (Small Entity)	65	—
1.16(f)	Design Filing Fee	320	330
1.16(f)	Design Filing Fee (Small Entity)	160	165
1.16(g)	Plant Filing Fee	530	540
1.16(g)	Plant Filing Fee (Small Entity)	265	270
1.16(h)	Reissue Filing Fee	770	790
1.16(h)	Reissue Filing Fee (Small Entity)	385	395
1.16(i)	Reissue Independent Claims	80	82
1.16(i)	Reissue Independent Claims (Small Entity)	40	41
1.16(j)	Reissue Claims in Excess of 20	22	—
1.16(j)	Reissue Claims in Excess of 20 (Small Entity)	11	—
1.16(k)	Provisional Application Filing Fee	150	—
1.16(k)	Provisional Application Filing Fee (Small Entity)	75	—
1.16(l)	Surcharge—Incomplete Provisional App. Filed	50	—
1.16(l)	Surcharge—Incomplete Provisional App. Filed (Small Entity)	25	—
1.17(a)	Extension—First Month	110	—
1.17(a)	Extension—First Month (Small Entity)	55	—
1.17(b)	Extension—Second Month	390	400
1.17(b)	Extension—Second Month (Small Entity)	195	200
1.17(c)	Extension—Third Month	930	950
1.17(c)	Extension—Third Month (Small Entity)	465	475
1.17(d)	Extension—Fourth Month	1,470	1,510
1.17(d)	Extension—Fourth Month (Small Entity)	735	755
1.17(e)	Notice of Appeal	300	310
1.17(e)	Notice of Appeal (Small Entity)	150	155
1.17(f)	Filing a Brief	300	310
1.17(f)	Filing a Brief (Small Entity)	150	155
1.17(g)	Request for Oral Hearing	260	270
1.17(g)	Request for Oral Hearing (Small Entity)	130	135
1.17(h)	Petition—Not All Inventors	130	—
1.17(h)	Petition—Correction of Inventorship	130	—
1.17(h)	Petition—Decision on Questions	130	—
1.17(h)	Petition—Suspend Rules	130	—
1.17(h)	Petition—Expedited License	130	—
1.17(h)	Petition—Scope of License	130	—
1.17(h)	Petition—Retroactive License	130	—
1.17(h)	Petition—Refusing Maintenance Fee	130	—
1.17(h)	Petition—Refusing Maintenance Fee—Expired Patent	130	—
1.17(h)	Petition—Interference	130	—
1.17(h)	Petition—Reconsider Interference	130	—
1.17(h)	Petition—Late Filing of Interference	130	—
1.20(b)	Petition—Correction of Inventorship	130	—
1.17(h)	Petition—Refusal to Publish SIR	130	—
1.17(i)	Petition—For Assignment	130	—
1.17(i)	Petition—For Application	130	—
1.17(i)	Petition—Late Priority Papers	130	—
1.17(i)	Petition—Suspend Action	130	—
1.17(i)	Petition—Divisional Reissues to Issue Separately	130	—
1.17(i)	Petition—For Interference Agreement	130	—
1.17(i)	Petition—Amendment After Issue	130	—
1.17(i)	Petition—Withdrawal After Issue	130	—
1.17(i)	Petition—Defer Issue	130	—
1.17(i)	Petition—Issue to Assignee	130	—
1.17(i)	Petition—Accord a Filing Date Under § 1.53	130	—
1.17(i)	Petition—Accord a Filing Date Under § 1.62	130	—
1.17(i)	Petition—Make Application Special	130	—
1.17(j)	Petition—Public Use Proceeding	1,470	1,510
1.17(k)	Non-English Specification	130	—

37 CFR Sec.	Description	Pre-Oct 1997	Oct 1997
1.17(l)	Petition—Revive Abandoned Appl.	110	—
1.17(l)	Petition—Revive Abandoned Appl. (Small Entity)	55	—
1.17(m)	Petition—Revive Unintentionally Abandoned Appl.	1,290	1,320
1.17(m)	Petition—Revive Unintent Abandoned Appl. (Small entity)	645	660
1.17(n)	SIR—Prior to Examiner's Action	900	920
1.17(o)	SIR—After Examiner's Action	1,790	1,840
1.17(p)	Submission of an Information Disclosure Statement (§ 1.l97)	230	240
1.17(q)	Petition—Correction of Inventorship (Prov. App.)	50	—
1.17(q)	Petition—Accord a filing date (Prov. App.)	50	—
1.17(q)	Petition—Entry of submission after final rejection (Prov. App.)	50	—
1.17(r)	Filing a submission after final rejection (1.129(a))	770	790
1.17(r)	Filing a submission after final rejection (1.129(a)) (Small Entity)	385	395
1.17(s)	Per add'l invention to be examined (1.129(b))	770	790
1.17(s)	Per add'l invention to be examined (1.129(b)) (Small Entity)	385	395
1.18(a)	Issue Fee	1,290	1,320
1.18(a)	Issue Fee (Small Entity)	645	660
1.18(b)	Design Issue Fee	440	450
1.18(b)	Design Issue Fee (Small Entity)	220	225
1.18(c)	Plant Issue Fee	650	670
1.18(c)	Plant Issue Fee (Small Entity)	325	335
1.19(a)(1)(i)	Copy of Patent	3	—
1.19(a)(1)(ii)	Patent Copy—Overnight delivery to PTO Box or overnight fax	6	—
1.19(a)(1)(iii)	Patent Copy Ordered by Expedited Mail or Fax—Exp. service	25	—
1.19(a)(2)	Plant Patent Copy	12	15
1.19(a)(3)(i)	Copy of Utility Patent or SIR in Color	24	25
1.19(b)(1)(i)	Certified Copy of Patent Application as Filed	15	—
1.19(b)(1)(ii)	Certified Copy of Patent Application as Filed, Expedited	30	—
1.19(b)(2)	Cert. or Uncert. Copy of Patent-Related File Wrapper/Contents	150	—
1.19(b)(3)	Cert. or Uncert. Copies of Office Records, Per Document	25	—
1.19(b)(4)	For Assignment Records, Abstract of Title and Certification	25	—
1.19(c)	Library Service	50	—
1.19(d)	List of Patents in Subclass	3	—
1.19(e)	Uncertified Statement-Status of Maintenance Fee Payment	10	—
1.19(f)	Copy of Non-U.S. Patent Document	25	—
1.19(g)	Comparing and Certifying Copies, Per Document, Per Copy	25	—
1.19(h)	Duplicate or Corrected Filing Receipt	25	—
1.20(a)	Certificate of Correction	100	—
1.20(c)	Reexamination	2,460	2,520
1.20(d)	Statutory Disclaimer	110	—
1.20(d)	Statutory Disclaimer (Small Entity)	55	—
1.20(e)	Maintenance Fee—3.5 Years	1,020	1,050
1.20(e)	Maintenance Fee—3.5 Years (Small Entity)	510	525
1.20(f)	Maintenance Fee—7.5 Years	2,050	2,100
1.20(f)	Maintenance Fee—7.5 Years (Small Entity)	1,025	1,050
1.20(g)	Maintenance Fee—11.5 Years	3,080	3,160
1.20(g)	Maintenance Fee—11.5 Years (Small Entity)	1,540	1,580
1.20(h)	Surcharge—Maintenance Fee—6 Months	130	—
1.20(h)	Surcharge—Maintenance Fee—6 Months (Small Entity)	65	—
1.20(i)(1)	Surcharge—Maintenance After Expiration—Unavoidable	680	700
1.20(i)(2)	Surcharge—Maintenance After Expiration—Unintentional	1,600	1,640
1.20(i)(1)	Extension of Term of Patent Under 1.740	1,090	1,120
1.20(j)(2)	Initial Application for Interim Extension Under 1.790	410	420
1.20(j)(3)	Subsequent Application for Interim Extension Under 1.790	210	220
1.21(a)(1)(i)	Application Fee (non-refundable)	40	—
1.21(a)(1)(ii)	Registration examination fee	300	310
1.21(a)(2)	Registration to Practice	100	—
1.21(a)(3)	Reinstatement to Practice	40	—
1.21(a)(4)	Certificate of Good Standing	10	—
1.21(a)(4)	Certificate of Good Standing, Suitable Framing	20	—
1.21(a)(5)	Review of Decision of Director, OED	130	—
1.21(a)(6)(i)	Regrading of A.M. section (PTO Practice and Procedure)	225	230
1.21(a)(6)(ii)	Regrading of P.M. section (Claim Drafting)	530	540
1.21(b)(1)	Establish Deposit Account	10	—
1.21(b)(2)	Service Charge Below Minimum Balance	25	—
1.21(b)(3)	Service Charge Below Minimum Balance	25	—
1.21(c)	Filing a Disclosure Document	10	—
1.21(d)	Box Rental	50	—
1.21(e)	International Type Search Report	40	—
1.21(g)	Self-Service Copy Charge	.25	—
1.21(h)	Recording Patent Property	40	—
1.21(i)	Publication in the OG	25	—
1.21(j)	Labor Charges for Services	30	40
1.21(k)	Unspecified Other Services	(1)	—

37 CFR Sec.	Description	Pre-Oct 1997	Oct 1997
1.21(k)	Terminal Use APS–CSIR (per hour)	50	—
1.21(l)	Retaining abandoned application	130	—
1.21((m)	Processing Returned Checks	50	—
1.21(n)	Handling Fee—Incomplete Application	130	—
1.21(o)	Terminal Use APS-TEXT	40	—
1.24	Coupons for Patent and Trademark Copies	3	—
1.296	Handling Fee—Withdrawal SIR	130	—
1.445(a)(1)	Transmittal Fee	230	240
1.445(a)(2)(i)	PCT Search Fee—Prior U.S. Application	440	450
1.445((a)(2)(ii)	PCT Search Fee—No U.S. Application	680	700
1.445(a)(3)	Supplemental Search	200	210
1.482(a)(1)(i)	Preliminary Exam Fee	480	490
1.482(a)(1)(ii)	Preliminary Exam Fee	730	750
1.482(a)(2)(i)	Additional Invention	140	—
1.482(a)(2)(ii	Additional Invention	260	270
1.492(a)(1)	Preliminary Examining Authority	700	720
1.492(a)(1)	Preliminary Examining Authority (Small Entity)	350	360
1.492((a)(2)	Searching Authority	770	790
1.492((a)(2)	Searching Authority (Small Entity)	385	395
1.492(a)(3)	PTO Not ISA nor IPEA	1,040	1,070
1.492(a)(3)	PTO Not ISA nor IPEA (Small Entity)	520	535
1.492(a)(4)	Claims—IPEA	96	98
1.492(a)(4)	Claims—IPEA (Small Entity)	48	49
1.492(a)(5)	Filing with EPO/JPO Search Report	910	930
1.492((a)(5)	Filing with EPO/JPO Search Report (Small Entity)	455	465
1.492(b)	Claims—Extra Individual (Over 3)	80	82
1.492(b)	Claims—Extra Individual (Over 3) (Small Entity)	40	41
1.492(c)	Claims—Extra Total (Over 20)	22	—
1.492(c)	Claims—Extra Total (over 20) (Small Entity)	11	—
1.492(d)	Claims—Multiple Dependents	260	270
1.492((d)	Claims—Multiple Dependents (Small Entity)	130	135
1.492((e)	Surcharge	130	—
1.492(e)	Surcharge (Small Entity)	65	—
1.492(f)	English Translation—After 20 Months	130	—
2.6(a)(1)	Application for Registration, Per Class	245	—
2.6(a)(2)	Amendment to Allege Use, Per Class	100	—
2.6(a)(3)	Statement of Use, Per Class	100	—
2.6(a)(4)	Extension for Filing Statement of Use, Per Class	100	—
2.6(a)(5)	Application for Renewal, Per Class	300	—
2.6(a)(6)	Surcharge for Late Renewal, Per Class	100	—
2.6(a)(7)	Publication of Mark Under §12(c), Per Class	100	—
2.6(a)(8)	Issuing New Certificate of Registration	100	—
2.6(a)(9)	Certificate of Correction of Registrant's Error	100	—
2.6(a)(10)	Filing Disclaimer to Registration	100	—
2.6(a)(11)	Filing Amendment to Registration	100	—
2.6(a)(12)	Filing Affidavit Under Section, 8 Per Class	100	—
2.6(a)(13)	Filing Affidavit Under Section 15, Per Class	100	
2.6(a)(14)	Filing Affidavit Under Sections 8 & 15, Per Class	200	—
2.6(a)(15)	Petitions to the Commissioner	100	—
2.6(a)(16)	Petition to Cancel, Per Class	200	—
2.6(a)(17)	Notice of Opposition, Per Class	200	—
2.6(a)(18)	Ex Parte Appeal to the TTAB, Per Class	100	—
2.6(a)(19)	Dividing an Application, Per New Application Created	100	—
2.6(b)(1)(i)	Copy of Registered Mark	3	—
2.6(b)(1)(ii)	Copy of Registered Mark, overnight delivery to PTO box or fax	6	—
2.6(b)(1)(iii)	Copy of Reg. Mark Ordered Via Exp. Mail or Fax, Exp. Svc	25	—
2.6(b)(2)(i)	Certified Copy of TM Application as Filed	15	—
2.6(b)(2)(ii)	Certified Copy of TM Application as Filed, Expedited	30	—
2.6(b)(b)(3)	Cert. or Uncert. Copy of TM-Related File Wrapper/Contents	50	—
2.6(b)(4)(i)	Cert. Copy of Registered Mark, Title or Status	10	15
2.6(b)(4)(ii)	Cert. Copy of Registered Mark, Title or Status—Expedited	20	30
2.6(b)(5)	Certified or Uncertified Copy of TM Records	25	—
2.6(b)(6)	Recording Trademark Property, Per Mark, Per Document	40	—
2.6(b)(6)	For Second and Subsequent Marks in Same Document	25	—
2.6(b)(7)	For Assignment Records, Abstracts of Title and Cert	25	—
2.6(b)(8)	Terminal Use X-SEARCH	40	—
2.6(b)(9)	Self-Service Copy Charge	0.25	—
2.6(b)(10)	Labor Charges for Services	30	—
2.6(b)(11)	Unspecified Other Services	[1]	—

—These fees are not affected by this rulemaking.
[1] Actual cost.

[FR Doc. 97–19901 Filed 7–28–97; 8:45 am]
BILLING CODE 3501–16–U–M

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

Copyright Rules and Regulations

AGENCY: Copyright Office, Library of Congress.
ACTION: Correction; technical amendments.

SUMMARY: The Copyright Office is making one correction to the non-substantive housekeeping amendments to its regulations published in the **Federal Register** July 1, 1997. The correction amends the address for the Licensing Division of the Copyright Office.
EFFECTIVE DATE: July 29, 1997.
FOR FURTHER INFORMATION CONTACT: Marilyn J. Kretsinger, Assistant General Counsel, or Patricia L. Sinn, Senior Attorney, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, DC 20024. Telephone: (202) 707–8380. Fax: (202) 707–8366.
SUPPLEMENTARY INFORMATION: The Copyright Office is correcting the address it published for the Office's Licensing Division in the July 1, 1997, edition of the **Federal Register**. The corrected address is effective immediately, and will appear in the Code of Federal Regulations at 37 CFR 201.1(b) as soon as possible.

List of Subjects in 37 CFR Part 201

Copyright, General Provisions.

Final Rule

Accordingly, 37 CFR Chapter II is corrected by making the following correction and amendment.

PART 201—GENERAL PROVISIONS

1. The authority citation for Part 201 continues to read as follows:
Authority: 17 U.S.C. 702, 17 U.S.C. 1003.

§ 201.1 [Amended]

2. Section 201.1(b) is amended by removing ''Licensing Division, LM–454, Library of Congress, Copyright Office, 101 Independence Avenue, SE., Washington, DC 20559–6000.'' and adding in its place ''Library of Congress, Copyright Office, Licensing Division, 101 Independence Avenue, SE., Washington, DC 20557–6400.''

Dated: July 23, 1997.

Marilyn J. Kretsinger,

Assistant General Counsel.

[FR Doc. 97–19904 Filed 7–28–97; 8:45 am]
BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD 038–3016; FRL–5864–9]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; 15% Rate of Progress Plan and Contingency Measures for the Cecil County Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: EPA is granting full approval of the State Implementation Plan (SIP) revision submitted by the State of Maryland, for Cecil County, part of the Philadelphia-Wilmington-Trenton severe ozone nonattainment area, to meet the 15 percent reasonable further progress (RFP, or 15% plan) requirements of the Clean Air Act (the Act). EPA is granting approval of the 15% plan and contingency measures, submitted by the State of Maryland, because the plan achieves the required 15% emission reduction. This action is being taken under section 110 of the Clean Air Act.

EFFECTIVE DATE: This final rule is effective on August 28, 1997.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland 21224.

FOR FURTHER INFORMATION CONTACT: Carolyn M. Donahue, (215) 566–2095, at the EPA Region III address above. Information may also be requested via e-mail at the following address: donahue.carolyn@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 182(b)(1) of the Act requires ozone nonattainment areas classified as moderate or above to develop plans to reduce volatile organic compounds (VOC) emissions by fifteen percent from 1990 baseline levels. Cecil County, as part of the Philadelphia-Wilmington-Trenton nonattainment area, is classified as severe and is subject to the 15% plan requirement.

The State of Maryland submitted the 15% plan SIP revision for Cecil County on July 12, 1995. On June 5, 1997, EPA published a notice of proposed rulemaking (NPR) in the **Federal Register** proposing approval of the 15% plan [62 FR 30818]. EPA's rationale for granting approval to the Maryland 15% plan for the Cecil County nonattainment area, and the details of the July 12, 1995 submittal are contained in the June 5, 1997 NPR and the accompanying technical support document and will not be restated here. No public comments were received on the NPR.

II. Final Action

EPA is today granting approval of the 15% plan and contingency measures for the Cecil County severe ozone nonattainment area as a revision to the Maryland SIP.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the EPA certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S.*

EPA, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

Under section 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by section 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action, pertaining to the final approval of the 15% plan for the Cecil County nonattainment area, must be filed in the United States Court of Appeals for the appropriate circuit by September 29, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Ozone.

Dated: July 18, 1997.

Thomas Voltaggio,

Acting Regional Administrator, Region III.

Chapter I, title 40, of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart V—Maryland

2. Section 52.1076 is added to read as follows:

§ 52.1076 Control strategy: ozone

EPA is approving as a revision to the Maryland State Implementation Plan the 15 Percent Rate of Progress Plan and associated contingency measures for the Cecil County ozone nonattainment area, submitted by the Secretary of the Maryland Department of the Environment on July 12, 1995.

[FR Doc. 97–19884 Filed 7–28–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN189–1–9730(b); TN194–1–9731(b); TN198–1–9732(b); FRL–5859–7]

Approval of Revisions to the Tennessee SIP Regarding Prevention of Significant Deterioration and Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving miscellaneous revisions to the Tennessee State Implementation Plan (SIP) regarding prevention of significant deterioration (PSD) and volatile organic compounds (VOC). The revisions to the PSD regulation add an additional supplement to the EPA ''Guideline on Air Quality Models.'' The revisions to the VOC regulation make minor changes to the regulation for the manufacture of high-density polyethylene, polypropylene and polystyrene resins and to the regulation containing test methods and compliance procedures for VOC sources.

DATES: This final rule is effective September 29, 1997, unless adverse or critical comments are received by August 28, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Written comments on this action should be addressed to William Denman at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. Copies of documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference files TN189–01–9730, TN194–01–9731, and TN198–01–9732. The Region 4 office may have additional background documents not available at the other locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460

Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. William Denman, 404/562–9030

Tennessee Department of Environment and Conservation, Division of Air Pollution Control, L & C Annex, 9th Floor, 401 Church Street, Nashville, Tennessee 37243–1531.

FOR FURTHER INFORMATION CONTACT: William Denman at 404/562–9030.

SUPPLEMENTARY INFORMATION: On August 9, 1995, EPA published a notice in the **Federal Register** (60 FR 40465), that took final action on several additions and changes to the ''Guideline on Air Quality Models'' in the PSD rules. These revisions were designated as supplement C to the ''Guideline on Air Quality Models.'' On February 27, 1997, Tennessee submitted to EPA a revision to Tennessee regulation 1200–3–9 ''Construction and Operating Permits'' in which Tennessee added supplement C to their already adopted by reference ''Guideline on Air Quality Models''. Supplement C incorporates improved algorithms for treatment of area sources and dry deposition in the Industrial Source Complex model, adopts a solar radiation/delta-T (SRDT) method for estimating atmospheric stability categories, and adopts a new screening approach for assessing annual NO_2 impacts. It also adds SLAB and HGSYSTEM as alternative models.

On May 8, 1997, Tennessee submitted to EPA a revision to the Tennessee regulation for the control of VOC

emissions from the manufacture of high-density polyethylene, polypropylene and polystyrene resins. This revision corrected a conversion factor for determining the mass rates of total VOC. The incorrect conversion factor of 2.95 x 10^{-9} was revised to be the correct factor of 2.595 x 10^{-9}.

On May 8, 1997, Tennessee also submitted to EPA a revision to the Tennessee regulation containing test methods and compliance procedures for determining the VOC content of coatings and inks. This revision provided clarification on which method should be used for various types of inks. The clarifying revision stated that Method 24A was for publication rotogravure inks and Method 24 was for all other inks and coatings.

Final Action

The EPA is approving the submitted revisions into the Tennessee SIP as described in the Supplementary Information section. The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective September 29, 1997 unless, by August 28, 1997, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent notice that will withdraw the final action. All public comments received will be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective September 29, 1997.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2) and 7410(k)(3).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by section 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 29, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Ozone, Reporting and recordkeeping requirements.

Dated: July 3, 1997.

Michael V. Peyton,

Acting Regional Administrator.

Part 52 of chapter I, title 40, Code of Federal Regulations, is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42.U.S.C. 7401–7671q.

Subpart RR—Tennessee

2. Section 52.2220, is amended by adding paragraph (c)(158) to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

(158) Addition of supplement C to the ''Guideline on Air Quality Models'', correction of conversion factor in the manufacture of high-density polyethylene, polypropylene and polystyrene resins, and clarification for the test method used for determining the VOC content of coatings and inks submitted by the Tennessee Department of Environment and Conservation on February 27, 1997, and May 8, 1997.

(i) Incorporation by reference.

(A) Tennessee regulation 1200–3–9–.01(1)(f) effective December 28, 1996.

(B) Tennessee regulations 1200–3–18–.39(5)(a)(2) and 1200–3–18–.81(2) (a) and (b) effective April 16, 1997.

(ii) Other material. None.

[FR Doc. 97–19937 Filed 7–28–97; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 61 and 69

[CC Docket Nos. 96–262, 94–1, 91–213, 96–263; FCC 97–158]

Access Charge Reform; Price Cap Performance Review for Local Exchange Carriers; Transport Rate Structure and Pricing; Usage of the Public Switched Network by Information Service and Internet Access Providers

AGENCY: Federal Communications Commission.

ACTION: Final rule; Correction.

SUMMARY: This document contains corrections to the summary of the Commission's Report and Order reforming access charges published in the **Federal Register** of June 11, 1997 (62 FR 31868).

EFFECTIVE DATE: June 11, 1997.

FOR FURTHER INFORMATION CONTACT: Richard Lerner, Attorney, Common Carrier Bureau, Competitive Pricing Division, (202) 418–1520, email: rlerner@fcc.gov.

SUPPLEMENTARY INFORMATION: The Commission published a summary of the Access Charge Reform First Report and Order (released May 7, 1997) in the **Federal Register** issue of June 11, 1997, in FR Doc. 97–14628 (62 FR 31868). The summary outlines an order that revised the current interstate access charge rules in order to promote local competition and to comply with the Telecommunications Act of 1996. This summary was published with some typographical mistakes and minor omissions. This document corrects those mistakes and omissions. The publication on June 11, 1997 of the Access Charge Reform First and Order summary (62 FR 3188), which was the subject of FR Doc. 97–14628, is corrected as follows:

1. On page 31868, in the first column, lines 4 and 5, replace ''[CC Docket Nos. 96–262, 94–1, 91–213, 96–263; FCC 97–158]'' with ''[CC Docket Nos. 96–262, 94–1, 91–213, 95–72; FCC 97–158]''.

2. On page 31868, in the first column under DATES:, line 27, replace ''and 69.156'' with ''69.201, 69.203, 69.204 and 69.205''.

3. On page 31931, in the first column, paragraph (i)(l), line 16, replace the phrase ''formula in § 61.44(b)'' with ''formula in § 61.45(c) and, pursuant to § 61.45(b), application of the formula in § 61.44(b)''.

4. On page 31931, in the first column, paragraph (i)(1), lines 22 and 23, replace the phrase ''formula in § 61.44(b)'' with ''formulas in § 61.44(b) and § 61.45(c)''.

5. On page 31931, in the first column, paragraph (i)(2), line 2, replace ''paragraphs (b) and (c)'' with ''paragraph (b)''.

6. On page 31931, in the first column, paragraph (i)(2), line 15, replace ''application of the formula'' with ''application, pursuant to § 61.45(b), of the formula''.

7. On page 31931, in the second column, paragraph (j), line 3, replace ''paragraphs (i)(1) and (i)(2)'' with ''paragraphs (i)(1) and (i)(1) of this section and § 61.47(i)(1) and (i)(2)''.

8. On page 31931, in the second column, paragraph (j), line 4, insert ''(1)'' after ''local exchange carriers shall''.

9. On page 31931, in the second column, paragraph (j), line 41, insert the following text after the word ''targeting'':

''(2) not include the amount of any exogenous adjustments reflected in the z component of the formulas in §§ 61.44(b) and 61.45(c). Any such exogenous adjustments shall be reflected in the various PCIs and SBIs in the same manner as they would if there were no targeting''.

10. On page 31931, in the third column, paragraph #5, lines 2 and 3, replace ''revising paragraphs (d) and (e) and adding new paragraphs (g) and (h)'' with

''redesignating the introductory text of paragraph (d) as the introductory text of paragraph (d)(1) and revising it, adding new paragraph (d)(2), redesignating paragraph (e) as paragraph (e)(1) and revising it, and adding new paragraphs (e)(2), (g) and (h)''.

11. On page 31932, in the first column, paragraph (i)(1), line 3, add ''and subject to the limitations of § 61.45(j),'' after ''paragraph (a) of this section,''.

12. On page 31932, in the second column, line 4, remove ''and (i)(1)'' and replace with ''and the formula in § 61.44(b) and from the application of the provisions of § 61.45(i)(1)''.

13. On page 31932, in the second column, paragraph (i)(2), line 3, add ''and subject to the limitations of § 61.45(j)'' after ''paragraph (a) of this section,''.

14. On page 31932, in the second column, paragraph (i)(2), line 11, replace ''61.45(b), (i)(1) and (i)(2)'' with ''61.45(b) and the formula in § 61.44(b) and from the application of the provisions of § 61.45 (i)(1) and (i)(2)''.

15. On page 31932, in the second column, paragraph (i)(3), lines 6–8, remove the following phrase: ''and from the application of § 61.45(b) to the basket described in § 61.42(d)(3)''.

16. On page 31932, in the second column, paragraph (i)(4), lines 6–8, remove the following phrase: ''and from the application of § 61.45(b) to the basket described in § 61.42(d)(3)''.

17. On page 31937, in the third column, paragraph (d)(2)(i), lines 4 and 5, replace ''this part and part 61'' with ''parts 61 and 69''.

18. On page 31938, in the first column, paragraph c in § 69.155, line 2, add ''s'' to the end of ''paragraph''.

19. On page 31938, in the third column, amendment #24, line 3, replace ''paragraph designation'' with ''designator''.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–19911 Filed 7–28–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 69

[CC Docket Nos. 96–262, 94–1, 91–213, 96–263; FCC 97–247]

Access Charge Reform; Price Cap Performance Review for Local Exchange Carriers; Transport Rate Structure and Pricing; Usage of the Public Switched Network by Information Service and Internet Access Providers

AGENCY: Federal Communications Commission.

ACTION: Final rule; sua sponte reconsideration.

SUMMARY: The Federal Communications Commission here reconsiders on its own

motion five specific issues addressed in its First Report and Order in this proceeding. First, the Commission corrects errors in the rules adopted in the First Report and Order in this proceeding that could permit rural incumbent local exchange carriers (rural incumbent LECs) to recover twice a portion of their local switching costs, that could be interpreted to require carriers to deduct a potentially improper long term support amount from the base factor portion of their common-line revenue requirement, and that could result in improper calculation of annual access minutes-of-use calculated by LECs for use in setting per-minute charges for shared multiplexers on the end office side of the tandem switch.

Second, the Commission clarified the steps non-price cap LECs should take to reassign the costs of trunk ports and multiplexers used at the tandem switch, and the costs of DS1/voice grade multiplexers used at the local switch, from the transport interconnection charge (TIC) rate element to the tandem switching rate element and the local switching rate element, respectively.

Third, the Commission clarified that price cap carriers may vary their tandem-switching charge in accordance with the part 61 price cap rules, even after reassigning to the tandem-switching rate element the portion of tandem switching costs now recovered through the TIC.

Fourth, the Commission revised its rules to revise the triggering point at which a price cap carrier should begin calculating its SLC based on average per-line common line revenues permitted under the price cap rules.

Fifth, the Commission reinstated a portion of its rules relating to general support facilities that we erroneously deleted in the First Report and Order.

EFFECTIVE DATE: The amendments to § 69.307(c) shall become effective August 28, 1997. The amendments to §§ 69.1(c), 69.106(b), 69.111(g)(4), 69.111(l)(1), 69.152(b), and 69.502(c) shall become effective January 1, 1998.

FOR FURTHER INFORMATION CONTACT: Rich Lerner or Richard Cameron, 202–418–1530.

SUPPLEMENTARY INFORMATION: Adopted: July 10, 1997; Released: July 10, 1997.

1. On May 7, 1997, we adopted the First Report and Order in this proceeding[1] and the Report and Order in our related Universal Service proceeding.[2] On our own motion, and upon further consideration of some of the issues addressed in our *Access Reform Order,* we take this opportunity to revise or clarify certain of our actions.[3]

I. DEM Weighting, Long Term Support, and Local Switching

2. *DEM Weighting.* In our *Universal Service Order,* among other actions, we provided that, on January 1, 1998, eligible rural telephone company study areas with fewer than 50,000 lines would begin receiving local switching support from the new universal service support mechanisms in an amount equal to the implicit support they formerly received from dial equipment minute-of-use (DEM) weighting.[4] We did not make clear in the *Access Reform Order,* however, how the switching rates for both incumbent LECs subject to price cap regulation and those that are not subject to price cap regulation would be affected by the new universal service mechanisms. The obvious solution is to permit rural incumbent LECs to recover these switching costs either from universal service support mechanisms or from interstate access charges, but not to permit recovery of these costs from both sources duplicatively.

3. The rules adopted to implement our *Access Reform Order* provide that the per-minute local switching charge to be imposed by incumbent LECs not subject to price cap regulation ''shall be computed by dividing the projected annual revenue requirement for the Local Switching element by the projected annual access minutes of use for all interstate or foreign services that use local exchange switching facilities.'' [5]

4. On further consideration of our revisions to § 69.106, we recognize that, absent further clarification, rural incumbent LECs not subject to price cap regulation may have the opportunity to recover twice a portion of their local switching costs. DEM weighting increases the interstate local switching revenue requirement when costs are separated in part 36 between the intrastate and interstate jurisdictions.[6] Although the *Universal Service Order* established a new mechanism for providing to carriers the amount of support that was formerly received from DEM weighting, it preserved the use of DEM weighting in assigning local switching revenue requirement to the interstate jurisdiction. Thus, if a rural incumbent LEC were to use the entire DEM-weighted interstate component of the part 36 local switching revenue requirement in setting access charges for local switching under § 69.106, it would have the opportunity to recover twice that portion of the interstate revenue requirement attributable to DEM-weighting. Specifically, the rural incumbent LEC would receive compensation for the DEM-weighted component of local switching from universal service support mechanisms, and also would be able to continue to set the local switching element of its access charges to recover the portion of its interstate revenue requirement attributable to DEM-weighting. Clearly, we did not intend our rules to permit such a result.

5. On our own motion, therefore, we take this opportunity to reconsider this issue and revise § 69.106.[7] We clarify that, in setting its per-minute access charge for local switching under § 69.106, each rural incumbent LEC not subject to price cap regulation must exclude from its local switching interstate revenue requirement any high-cost support attributable to DEM weighting.

6. Similarly, to the extent that any price cap LEC receives high-cost support attributable to DEM-weighting under § 54.301, we require such price cap LEC, in its access tariff filed reflecting its receipt of support under § 54.301, to make a downward exogenous adjustment to its traffic sensitive basket price cap index (PCI) and to its common line basket PCI to reflect the recovery of this amount from the new high-cost support mechanism. These exogenous adjustments must be made after the exogenous adjustments required when the price cap LEC reallocates the costs of line ports to the common line basket in accordance with the *Access Reform Order.*[8] The exogenous downward adjustment to each basket must be in proportion to the local switching costs contained within that basket. For

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[1] Access Charge Reform, First Report and Order, 62 FR 31838 (June 11, 1997) (*Access Reform Order*).

[2] Federal-State Joint Board on Universal Service, Report and Order, 62 FR 32862 (June 17, 1997) (*Universal Service Order*).

[3] *See* 47 CFR 1.108.

[4] 47 CFR 54.301. The jurisdictional separations process currently allocates local switching costs between the state and interstate jurisdictions on the basis of relative DEM. Carrier study areas with fewer than 50,000 lines receive support, until December 31, 1997, from DEM weighting, which shifts additional local switching costs to the interstate jurisdiction by multiplying the carrier's interstate DEM by a factor of up to 3.0. Until December 31, 1997, these weighted local switching costs will continue to be recovered from interexchange carriers through per-minute access charges for use of the local switch. Beginning in January 1998, rural incumbent LECs will receive explicit support from the new universal service support mechanisms equal to the amount previously collected as a result of DEM weighting. *Universal Service Order at* ¶¶*303–04.*

[5] 47 CFR 69.106(b).

[6] 47 CFR 36.125.

[7] *See 47 CFR 1.108.*

[8] *Access Reform Order* at ¶¶125–135.

example, if a price cap LEC makes exogenous adjustments to reallocate 30 percent of its local switching costs contained within the traffic sensitive basket to the common line basket, reflecting the costs of its line ports, it must then make a downward exogenous adjustment to the common line basket in an amount equal to 30 percent of the support it receives under § 54.301 and a downward exogenous adjustment to the traffic sensitive basket in an amount equal to the remaining 70 percent.

7. Long Term Support. We also modify the language of § 69.502(c) to clarify the per-line support amount that carriers should use in making deductions from the base factor portion of the common line element. In the *Universal Service Order*, we did not adopt the Joint Board's recommendation that, for the three years beginning January 1, 1998, high-cost support be calculated for rural incumbent LECs based on historic high-cost loop support, DEM weighting, and long term support (LTS) amounts.[9] Instead, consistent with the recommendation of the State High Cost Report [10] and of many commenters, high-cost support attributable to the former LTS mechanism may increase based on changes in the nationwide average loop cost.[11] We therefore replace the phrase ''frozen per-line support'' in § 69.502 with the phrase ''per-line support.''

8. Other Local Switching Issues. In the *Access Reform Order*, we directed incumbent LECs to set per-minute rates for the transmission component of tandem-switched transport using ''the total actual voice-grade minutes of use, geographically averaged on a study-area-wide basis, that the incumbent [LEC] experiences based on the prior year's annual use,'' [12] or averaged on a zone-wide basis where the incumbent LEC has implemented density pricing zones.[13] In new § 69.111(l), however, we directed incumbent LECs to develop per-minute charges for the shared multiplexers used on the end office side of the tandem switch, using as a denominator ''the projected annual access minutes of use calculated for purposes of recovery of common transport costs in paragraph (c) of this section.''[14] We will delete the word ''projected'' from this sentence of our rules. Paragraph (c) does not require a projection, but instead calls for the use of the prior year's historical data. For clarity, we also delete the extraneous phrase ''by the serving wire center side of the tandem switch'' from this section.

II. TIC Reduction for Non-Price Cap Incumbent LECs

9. In our *Access Reform Order*, we took steps to adopt a cost-based transport rate structure and to comply with the remand order issued by the United States Court of Appeals for the District of Columbia Circuit in *Competitive Telecommunications Ass'n v. FCC (CompTel)*.[15] In complying with the *CompTel* remand, we took steps to eliminate or substantially reduce the transport interconnection charge (TIC), which we originally created as part of our interim transport rate structure.[16]

10. We reassigned portions of the TIC to other rate elements, some of which were created in the *Access Reform Order* only for price cap carriers. In creating the new rate elements established for multiplexers used at the tandem switch, we ''direct[ed] incumbent LECs to establish separate rate elements for the multiplexing equipment on each side of the tandem switch.'' [17] This language potentially may be unclear, especially in light of subsequent language directing only ''price cap LECs [to] reallocate revenues'' to these rate elements.[18] As an initial matter, therefore, we here clarify that these rate elements apply only to price cap incumbent LECs.

11. We specifically directed carriers to reassign certain TIC amounts to newly created rate elements for trunk ports and multiplexers used at the tandem switch [19] and for DS1/voice grade multiplexers used at the local switch.[20] Because these rate elements were created only for price cap carriers, however, we take this opportunity to clarify the application of this section of our *Access Reform Order* with respect to incumbent LECs not subject to price cap regulation.

12. In access tariffs filed to become effective January 1, 1998, incumbent LECs not subject to price cap regulation should assign TIC amounts attributable to trunk ports and multiplexers used at the tandem switch to the tandem switching rate element. Even though the specific rate elements created for these amounts do not yet exist for non-price cap carriers, the amounts involved relate broadly to the use of the tandem switch. Similarly, in access tariffs filed to become effective January 1, 1998, incumbent LECs not subject to price cap regulation should assign TIC amounts attributable to DS1/voice grade multiplexers used at analog local switches to the local switching rate element for recovery. Even though the specific rate elements created for these amounts do not yet exist for non-price cap carriers, the amounts involved relate broadly to the use of analog local switches. We will consider whether these amounts should be further reallocated to individual rate elements in our upcoming rulemaking proceeding addressing access charge reform for rate-of-return carriers.

III. Reallocation of Tandem Switching Costs

13. Section 69.1(c) of our rules [21] limits the extent to which certain part 69 pricing rules apply to incumbent LECs subject to price cap regulation. Under the terms of § 69.1(c), while a price cap LEC uses these part 69 rules, *inter alia*, to set initial charges for new rate elements, the price cap LEC thereafter has discretion to vary these charges, subject to the limitations of the relevant price cap index and any applicable service category banding constraints.

14. Section 69.111(g) governs the reallocation by all carriers of tandem switching amounts currently being recovered through the TIC to the tandem switching rate element. As our rules are currently constructed, § 69.1(c) limits the extent to which § 69.111(g)(1) applies to price cap carriers, as described above, but §§ 69.111(g)(2) and 69.111(g)(3) are not so limited. We therefore revise § 69.1(c) to clarify that §§ 69.111(g)(2) and 69.111(g)(3) apply to price cap carriers only to the same extent as § 69.111(g)(1). To reallocate tandem switching amounts as described in § 69.111(g), price cap LECs must make downward exogenous adjustments to the interconnection charge service band index (SBI) and corresponding upward exogenous adjustments to the tandem-switched transport SBI at the times and in the amounts prescribed in § 69.111(g)(1–3).[22] Thereafter, they may vary the tandem-switching charge in

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[9] *Universal Service Order* at ¶¶297–99, 305–306.

[10] State Members' Report on the Use of Cost Proxy Models, dated March 26, 1997 (contained in the record of Federal-State Joint Board on Universal Service, CC Docket No. 96–45).

[11] *Universal Service Order* at ¶¶305–306. *See* 47 CFR 54.303.

[12] 47 CFR 69.111(c).

[13] 47 CFR 69.111(c)(2)(ii).

[14] 47 CFR 69.111(l)(1).

[15] 87 F.3d 522 (D.C. Cir. 1996).

[16] *Access Reform Order* at ¶¶210–243. The TIC was created as part of the interim transport rate structure adopted in Transport Rate Structure and Pricing, Report and Order and Further Notice of Proposed Rulemaking, 57 FR 54717 (November 20, 1992).

[17] *Access Reform Order* at ¶170.

[18] *Id. at* α *173.*

[19] *Access Reform Order* at ¶¶171–173.

[20] *Access Reform Order* at ¶¶218–219.

[21] 47 CFR 69.1(c).

[22] *See Access Reform Order* at ¶ 228.

accordance with the part 61 price cap rules.

IV. Common Line Issues

15. In the *Access Reform Order,* we directed each price cap carrier to calculate its subscriber line charge (SLC) based on the full average per-line interstate allocation of the common line revenue requirement, until its primary interexchange carrier charge (PICC) assessed on multi-line business (MLB) lines no longer recovers any common line revenues. At that time, we directed the price cap carrier to begin calculating the SLC based on average per-line common line revenues permitted under our price cap rules.[23] In certain situations, when the MLB PICC no longer recovers common line revenues, recalculation of the SLC may in turn create a common line residual to be recovered by the MLB PICC, making it impossible for the price cap LEC to develop a proper rate. Accordingly, we reconsider this aspect of our PICC rules, and take this opportunity to revise the triggering point at which a price cap carrier should begin calculating its SLC based on average per-line common line revenues permitted under the price cap rules. A price cap carrier should make this change in its SLC calculation when the maximum PICC assessed on primary residential lines, plus the maximum SLC on those lines, recovers the full amount of its per-line common line price cap revenues.

V. General Support Facilities

16. We also here reinstate portions of § 69.307(c), relating to general support facilities (GSF), that were erroneously deleted in the *Access Reform Order.* We will address GSF cost allocation issues in a future order in this proceeding.

VI. Final Regulatory Flexibility Analysis

17. In the *Access Reform Order,* we conducted a Final Regulatory Flexibility Analysis, as required by section 603 of the Regulatory Flexibility Act, as amended by the Contract With America Advancement Act of 1996, Public Law 104–121, 110 Stat. 847 (1996).[24] The changes we adopt in this Order do not affect that analysis.

VII. Ordering Clauses

18. Accordingly, it is ordered, pursuant to sections 1–4, 201–205, 251, 254, 303, and 405 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 201–205, 251, 254, 303 and 405, and pursuant to section 1.108 of the Commission's rules, 47 CFR § 1.108, that this Order on Reconsideration is adopted.

19. It is further ordered that § 69.307(c) of the Commission's rules, 47 CFR § 69.307(c) is amended as set forth below, effective August 28, 1997.

20. It is further ordered that §§ 69.1(c), 69.106(b), 69.111(g)(4), 69.111(l)(1), 69.152(b), and 69.502(c) of the Commission's rules, 47 CFR 69.1(c), 69.106(b), 69.111(g)(4), 69.111(l)(1), 69.152(b), and 69.502(c), are amended as set forth below, effective January 1, 1998.

List of Subjects in 47 CFR Part 69

Communications common carriers, Telephone.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

47 CFR, Part 69, is amended as follows:

PART 69—ACCESS CHARGES

1. The authority citation for part 69 continues to read as follows:

Authority: 47 U.S.C. 154(i) and (j), 201, 202, 203, 205, 218, 254, and 403.

2. Section 69.1(c) is revised to read as follows:

§ 69.1 Application of access charges.

* * * * *

(c) The following provisions of this part shall apply to telephone companies subject to price cap regulation only to the extent that application of such provisions is necessary to develop the nationwide average carrier common line charge, for purposes of reporting pursuant to §§ 43.21 and 43.22 of this chapter, and for computing initial charges for new rate elements: §§ 69.3(f), 69.106(b), 69.106(f), 69.106(g), 69.109(b), 69.110(d), 69.111(c), 69.111(g)(1), 69.111(g)(2), 69.111(g)(3), 69.111(l), 69.112(d), 69.114(b), 69.114(d), 69.125(b)(2), 69.301 through 69.310, and 69.401 through 69.412. The computation of rates pursuant to these provisions by telephone companies subject to price cap regulation shall be governed by the price cap rules set forth in part 61 of this chapter and other applicable Commission rules and orders.

3. Section 69.106(b) is revised to read as follows:

§ 69.106 Local switching.

* * * * *

(b) The per minute charge described in paragraph (a) of this section shall be computed by dividing the projected annual revenue requirement for the Local Switching element, excluding any local switching support received by the carrier pursuant to § 54.301 of this chapter, by the projected annual access minutes of use for all interstate or foreign services that use local exchange switching facilities.

* * * * *

4. Sections 69.111 (g)(4) and (l)(1) are revised to read as follows:

§ 69.111 Tandem Switched Transport and Tandem Charge.

* * * * *

(g) * * *

(4) A local exchange carrier that is subject to price cap regulation as that term is defined in § 61.3(x) of this chapter shall calculate its tandem switching revenue requirement as used in this paragraph by dividing the tandem switching revenue requirement that was included in the original interconnection charge by the original interconnection charge, and then multiplying this result by the annual revenues recovered through the interconnection charge, described in § 69.124, as of June 30, 1997. A local exchange carrier that is subject to price cap regulation as that term is defined in § 61.3(x) of this chapter shall then make downward exogenous adjustments to the service band index for the interconnection charge service category (defined in § 61.43(e)(2)(vi) of this chapter) and corresponding upward adjustments to the service band index for the tandem-switched transport service category (defined in § 61.43(e)(2)(v) of this chapter) at the times and in the amounts prescribed in paragraphs (g)(1) through (g)(3) of this section.

* * * * *

(l) * * *

(1) Local exchange carriers must establish a traffic-sensitive charge for DS3/DS1 multiplexers used on the end office side of the tandem switch, assessed on purchasers of common transport to the tandem switch. This charge must be expressed in dollars and cents per access minute of use. The maximum charge shall be calculated by dividing the total costs of the multiplexers on the end office-side of the tandem switch by the annual access minutes of use calculated for purposes of recovery of common transport costs in paragraph (c) of this section. A similar charge shall be assessed for DS1/voice-grade multiplexing provided on the end-office side of analog tandem switches.

* * * * *

5. Section 69.152(b) is revised to read as follows:

[23] *E.g., Access Reform Order* at ¶ 102.

[24] *Access Reform Order* at ¶¶ 419–440.

§ 69.152 End user common line for price cap local exchange carriers.

* * * * *

(b) Except as provided in paragraphs (d) through (i) of this section, the maximum single line rate or charge shall be computed:

(1) By dividing one-twelfth of the projected annual revenue requirement for the End User Common Line element by the projected average number of local exchange service subscriber lines in use during such annual period, only so long as a per-minute carrier common line charge is assessed or the maximum PICC assessed on primary residential lines, plus the maximum end user common line charge for primary residential lines, does not recover the full amount of its per-line common line price cap revenues; (and/or)

(2) by dividing one-twelfth of the projected annual revenues permitted for the common line basket under the Commission's price cap rules, as set forth in Part 61 of this chapter, by the projected average number of local exchange service subscriber lines in use during such annual period, if no per-minute carrier common line charge is assessed and the maximum PICC assessed on primary residential lines, plus the maximum end user common line charge for primary residential lines, recovers the full amount of its per-line common line price cap revenues.

* * * * *

6. Section 69.307(c) is added to read as follows:

§ 69.307 General support facilities.

* * * * *

(c) All other General Support Facilities investments shall be apportioned among the interexchange category, the billing and collection category, and Common Line, Local Switching, Information, Transport, and Special Access elements on the basis of Central Office Equipment, Information Origination/Termination Equipment, and Cable and Wire Facilities, combined.

7. Section 69.502(c) is revised to read as follows:

§ 69.502 Base factor allocation.

* * * * *

(c) The portion of per-line support that carriers receive pursuant to § 54.303.

[FR Doc. 97–19912 Filed 7–28–97; 8:45 am]

BILLING CODE 6712–01–P

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

48 CFR Parts 701, 702, 703, 704, 705, 706, 708, 709, 711, 715, 716, 717, 719, 722, 724, 725, 726, 728, 731, 732, 733, 734, 736, 749, 750, 752, 753, and Appendices A, C, G, and H to Chapter 7

[AIDAR Notice 97–1]

RIN 0412–AA30

Miscellaneous Amendments to Acquisition Regulations

AGENCY: Agency for International Development (USAID), IDCA.

ACTION: Final rule.

SUMMARY: The USAID Acquisition Regulation (AIDAR) is being amended to implement the Agency's new regulation on Source, Origin, and Nationality; to reflect the omission of authority for the Agency's Disadvantaged Enterprises Program in the 1996 and 1997 Appropriations Acts; to remove certification requirements not approved by the Head of the Agency in accordance with the Federal Acquisition Reform Act of 1996 (now known as the Clinger-Cohen Act of 1996); and to incorporate numerous administrative changes which correct mistakes, clarify or simplify policies or procedures currently in the AIDAR, and bring the AIDAR into compliance with Agency policies. This regulatory action was subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

EFFECTIVE DATE: August 28, 1997.

FOR FURTHER INFORMATION CONTACT: M/OP/P, Ms. Diane M. Howard, (703) 875–1310.

SUPPLEMENTARY INFORMATION: The specific changes being made to the USAID Acquisition Regulation (AIDAR) in this amendment are broad in scope, ranging from correcting typographical errors published over the past several years to implementing statutory requirements such as the loss of the Agency's Disadvantaged Enterprises Program (DEP) and removing unnecessary certification requirements.

A. Source, Origin, and Nationality

USAID published its final rule on Source, Origin, and Nationality, 22 CFR Part 228, on October 15, 1996 (61 FR 53615, corrected at 61 FR 54849 and 55361, and 62 FR 314). The AIDAR implements this regulation by revising section 702.170–15 and several sections in subpart 725.70, removing the clauses at 752.7004 (this number is used for a new clause as described in amendment 63) and 752.7017, and by adding clauses 752.255–70 and 752.225–71.

B. Disadvantaged Enterprises Program (DEP)

For years, USAID was required by law to ensure that at least 10% of its funds for development assistance or for assistance for famine recovery and development in Africa went to small disadvantaged business enterprises; however, not until FY 1990 did Congress provide the Agency with statutory authority to limit full and open competition solely for the purpose of meeting this set-aside requirement. AIDAR 706.302–71 was amended to implement the statutory authority. Statutory authority continued to be provided each year after that until FY 1996, when Congress did not provide the Agency with the statutory authority or impose the 10% ''set-aside'' requirement. Since the FY 1997 Appropriations Act did not include the authority, either, and indications are that the authority is not expected to be reinstated, we are amending the AIDAR to restrict the use of the authority in 706.302–71 to use other than full and open competition to award contracts to eligible disadvantaged business concerns (as defined in 726.7002) only to contracts funded from those fiscal years for which the statutory authority was provided. Subparts 706.302–71 and 726.70, and sections 705.207, 706.302–5, 726.7001, 726.7003, and 726.7007 are amended accordingly.

C. Contractor Certification Requirements

Section 4301 of the Clinger-Cohen Act required the removal of contractor and offeror certification requirements that are not: (1) Specifically imposed by statute, or (2) justified by the Senior Procurement Executive and approved by the Agency Head. On October 10, 1996, the USAID Administrator approved the retention of the AIDAR certifications found at sections 715.413–2 (which is also amended to remove paragraph (c) since the Procurement Integrity Certification requirement was removed from the FAR), 752.7001, and 752.7016(c)(3) (other certifications required in AIDAR Appendices D and J are addressed in a separate Final Rule). The certifications in 752.226–2(c)(3) and 752.7004(b)(5) are removed as described in B and A above, respectively (for the latter, the entire clause is removed and a new clause without certification requirements is added at 752.225–70). Section 752.7033(a) is amended to remove the physician's certification and

replace it with a ''statement of medical opinion''.

D. Administrative Changes

(1) The most pervasive administrative change to the AIDAR at this time is the conversion of the Agency's acronym from ''AID'' to ''USAID'' and the Agency's name from ''Agency for International Development'' to ''U.S. Agency for International Development''. the first seven amendments and Amendment 13 below are solely to effect this change, which is also part of several other amendments.

(2) In an effort to be comprehensive in implementing the simplified acquisitions procedures of the Federal Acquisition Streamlining Act of 1994 (FASA), when we amended the AIDAR on July 26, 1996 (AIDAR Notice 96–1, 61 FR 39089), we included both FAR 13.101 and 13.103(b) in several references to the simplified acquisition threshold. FAC 90–40 (61 FR 39185, published on the same day as the aforementioned AIDAR amendment) amended the FAR to delete ''interim FACNET certification'' (previously required in FAR 13.103(b)) and to allow all agencies to use $100,000 as the simplified acquisition threshold until December 31, 1999, after which time those agencies who have not certified full FACNET capability will be reduced to the $50,000 threshold, in accordance with the Clinger-Cohen Act of 1996. This FAC also moved the definition of ''simplified acquisition threshold'' to FAR 2.101 from section 13.101 (thereby rendering our AIDAR amendment inaccurate). To be consistent with the FAR, which doesn't include references to either section after most mentions of the simplified acquisition threshold, we are removing references to sections 13.101 and 13.103(b) when using the terms ''simplified acquisitions'' or ''the simplified acquisition threshold'' in the AIDAR.

(3) Prior to AIDAR Notice 96–1, the heads of the various Agency contracting activities had authority to redelegate small purchase contracting authority to persons on his or her staff; reflecting the conversion from ''small purchases'' to ''simplified acquisitions'', AIDAR Notice 96–1 increased the amount of contracting authority the HCAs can redelegate to the simplified acquisition threshold. However, in view of the change in the simplified acquisition threshold resulting from the Clinger-Cohen Act and the fact that few of the Agency HCAs have exercised this particular authority, we determined that limiting to $50,000 the level of contracting authority that they may redelegate would be an equitable balance between empowering the contracting activities and keeping prudent controls over the Agency's contracting authority; section 701.601 is amended accordingly.

(4) Because of a reorganization within the Agency, the Office of Administrative Services (M/AS) is no longer a contracting activity, nor is its Director the Metric Executive. Sections 702.170–3, 702.170–10, and 711.022–70 are amended to reflect this change.

(5) Sections 704.404 and 752.204–2 are amended to replace the term ''Limited Official Use'' with ''Sensitive But Unclassified'' in accordance with the State Department's revised policy found in Volume 12 of the Foreign Affairs Manual, Chapter 540.

(6) Section 705.002 is amended to state USAID policy to include all Commerce Business Daily notices and solicitations on the internet.

(7) Section 706.302–70 was amended in AIDAR Notice 96–1 to add a new Agency exception to full and open competition for follow-on awards; however, the actual wording was ambiguous as to whether the Agency Competition Advocate's approval was required concurrent with the approvals in FAR 6.304 or was the sole approval required for the new exception. The AIDAR is hereby amended to clarify that the use of this follow-on authority is subject only to the Agency Competition Advocate's approval if the action is over $250,000 or for more than one year, and to the contracting officer's certification for all other cases.

(8) Subpart 709.4 is amended to remove the Policy statement in 709.402, since it is redundant to other regulations (the FAR and 22 CFFR Part 208) on debarment and suspension of organizations under government procurement and non-procurement programs; however, we are adding a new section 709.403 to define the Agency's debarring and suspending official as the Procurement Executive.

(9) Section 715.613–71 is being amended to clarify procedures to be followed prior to processing a contract using the collaborative assistance method for activities authorized under Title XII of the Foreign Assistance Act of 1961.

(10) Section 752.209–70, entitled ''Requirement for Past Performance References'', is removed since it is redundant to FAR Subpart 9.1 and Agency procedures described elsewhere and is not needed in this Regulation.

(11) Several clause prescriptions in Subpart 752.70 are amended to clarify that these clauses are not to be used for commercial item contracts; the specific sections are 752.245–70, 752.245–71, 752.7008, 752.7070, 752.7015, and 752.7029. Other clauses being amended to clarify their prescriptions are 752.7001, which is being divided into two separate clauses because of the difference in the applicability of paragraphs (a) and (b) (the latter paragraph is now designated as section 752.7004), and section 752.7027, which is only to be used with services contracts.

(12) Over the past few years, the Agency has instituted a new system of internal directives, regulations and procedures to replace the old ''Handbook'' system. Since the new system (the Automated Directives System or ADS), when completed, will be a comprehensive reference source for all Agency policies and procedures, we are looking carefully at policies and procedures located in the AIDAR to determine if they should continue to be located in this published regulation or if they should instead be located only in the ADS. Consequently, we are removing several Appendices to the AIDAR and will be incorporating them in the near future into the ADS system, with reference to the appropriate ADS chapter in the AIDAR as needed. Specifically, Appendix A (''Respective Roles of Contracting and Other Personnel in the USAID Procurement Process''), Appendix C (''Logistics Support Overseas to USAID-Direct Contractors''), Appendix G ('Approval Procedures for Contractor Salaries''), and Appendix H (''Response to audit Recommendations'') are removed and reserved. A new section 701.602–1 is added to state the authority of contracting officers to negotiate and enter into settlements with contractors for costs questioned under audit reports, or to issue a contracting officer's final decision, and to refer to the appropriate ADS Chapters for policies and procedures for resolving audit recommendations. References to these appendices are revised elsewhere in the AIDAR, and section 701.376–3 is revised to more accurately describe the purpose of the remaining appendices to Chapter 7.

(13) Other administrative changes amend the expiration date of the OMB Control Number for all the information collections listed in 701.105; add a new section 703.104–11 to clarify to whom the contracting officer shall forward information and documentation on possible procurement integrity violations; remove Subpart 703.4 (''Contingent Fees'') to be consistent with the revisions to FAR 3.404 resulting from FAC 90–40; remove section 704.803 because it is internal procedural guidance better handled

outside published regulations; remove Part 708 because there is no longer an excess property handbook in the Agency; amend sections 731.205–6, 731.371, and 752.7007 to clarify the contracting officer's responsibility in approving salaries over the ES–6 threshold; revise 750.711 to update the procedures for processing cases of Extraordinary Contractual Relief; amend sections 752.228–7 and 752.7003 to update reference to the appropriate audit clause in the FAR; and to update the office acronym in section 753.107.

(14) Numerous errors and omissions were identified in Chapter 7 as published and are corrected in this rule, specifically in sections 701.373, 709.503, 711.022–70 (now redesignated as 711.002–70), 715.613–71, 719.271–3, 726.7005, 726.7006, 732.401, 733.270–2, 750.7101, 750.7109–3, 752.200, 752.219–8, 752.225–9, 752.226–1, 752.226–2, 752.226–3, 752.7027, and 752.7033.

The changes being made by this rule are not considered ''significant'' under FAR 1.301 or FAR 1.501, and public comments have not been solicited. This rule will not have an impact on a substantial number of small entities nor does it establish a new collection of information as contemplated by the Regulatory Flexibility Act and the Paperwork Reduction Act. Because of the nature and subject matter of this rule, use of the proposed rule/public comment approach was not considered necessary. We decided to issue as a final rule; however, we welcome public comment on the material covered by this rule or any other part of the AIDAR at anytime. Comments or questions may be addressed as specified in the **FOR FURTHER INFORMATION CONTACT** section of the Preamble.

List of Subjects in 48 CFR Parts 701, 702, 703, 704, 705, 706, 708, 709, 711, 715, 716, 717, 719, 722, 724, 725, 726, 728, 731, 732, 733, 734, 736, 749, 750, 752, and 753

Government procurement.

For the reasons set out in the Preamble, 48 CFR Chapter 7 is amended as set forth below.

1. The authority citations in Parts 701, 702, 703, 704, 705, 706, 708, 709, 711, 715, 716, 717, 719, 722, 724, 725, 726, 728, 731, 732, 733, 734, 736, 749, 750, 752, and 753 continue to read as follows:

Authority: Sec. 621, Pub. L. 87–195, 75 Stat. 445, (22 U.S.C. 2381) as amended; E.O. 12163, Sept. 29, 1979, 44 FR 56673; 3 CFR 1979 Comp., p. 435.

CHAPTER 7—[AMENDED]

2. Chapter 7 is amended by revising the acronym ''AID'' wherever it appears to read ''USAID''

3. Chapter 7 is amended by revising the possessive acronym ''AID's wherever is appears to read ''USAID's''.

4. Chapter 7 is amended by adding ''U.S.'' in front of ''Agency for International Development'' wherever it appears.

5. Chapter 7 is amended by revising ''AID/Washington'' wherever it appears in the following sections to read ''USAID/Washington'': 719.270, 719.271–6, 719.271–2, 752.7002.

6. Chapter 7 is amended by revising ''AID-direct'' wherever it appears in each of the following sections to read ''USAID-direct'': 711.002–71, 728.309, 752.7002, 722.170, 728.313, 752.7003, 728.307–2, 752.211–70.

7. Chapter 7 is amended by revising ''AID-financed'' wherever it appears in each of the following sections to read ''USAID-financed'': 725.703, 752.7004, 728.305–70, 752.7009.

PART 701—FEDERAL ACQUISITION REGULATION SYSTEM

701.105 [Amended]

8. The chart in paragraph (a) of section 701.105 is amended by revising the date ''09/30/96'' wherever it appears to read ''06/30/97''.

701.373 [Amended]

9. Paragraph (b) of section 701.373 is amended by revising ''69'' wherever it appears to read ''53''.

701.376–3 [Revised]

10. Section 701.376–3 is revised to read as follows:

701.376–3 Appendices

Significant procurement policies and procedures which do not correspond to or conveniently fit into the FAR system (described in FAR 1.1 and this subpart) may be published as Appendices to the AIDAR. Appendices follow the main text of the AIDAR in a section entitled ''Appendices to Chapter 7'' and contain the individual appendices identified by letter and subject title (e.g., ''Appendix D—Direct USAID Contracts with a U.S. Citizen or a U.S. Resident Alien for Personal Services Abroad'').

701.601 [Amended]

11. Section 701.601 is amended in paragraph (a) by revising the parenthetical phrase ''(see 701.376–4)'' at the end of the paragraph to read '', such as those found at 701.376–4 and particularly 701.603–70, the USAID policy regarding the direct-hire status of contracting officers''; and in paragraph (b) by removing the phrase ''the amount permitted by FAR 13.101 and 13.103(b)'' wherever it appears and inserting in its place ''$50,000'', by removing paragraph (b)(3), and by redesignating paragraphs (b)(4) and (5) as (b)(3) and (4), respectively.

12. A new Section 701.602–1 is added to read as follows:

701.602–1 Authority of contracting officers in resolving audit recommendations.

With the exception of termination settlements subject to part 749, Termination of Contracts, contracting officers shall have the authority to negotiate and enter into settlements with contractors for costs questioned under audit reports, or to issue a contracting officer's final decision pursuant to the disputes clause (in the event that questioned costs are not settled by negotiated agreement) in accordance with ADS Chapter 591.5.20. The negotiated settlement or final decision shall be final, subject only to a contractor's appeal, either under the provisions of the Contract Disputes Act of 1978, as amended (41 U.S.C. 601–613), or to the courts. Policies and procedures for resolving audit recommendations are in accordance with ADS Chapters 591 and 592.

701.704 [Amended]

13. Section 701.704 is amended by adding ''US'' to the beginning of ''AID-prescribed''.

PART 702—DEFINITIONS OF WORDS AND TERMS

702.170–3 [Amended]

14. Paragraph (a) of section 702.170–3 is amended by removing '', Office of Administrative Services'' in the first sentence.

702.170–10 [Amended]

15. Paragraph (a)(1) of section 702.170–10 is amended by revising ''AID/Washington'' to read ''USAID/Washington'', by removing paragraph (a)(1)(ii) and by redesignating paragraphs (a)(1)(iii) and (a)(1)(iv) as (a)(1)(ii) and (a)(1)(iii), respectively.

702.170–15 [Amended]

16. Section 702.170–15 is amended by revising ''a Free World Country (i.e., Geographic Code 935)'' to read ''a country included in Geographic Code 935 (see 22 CFR 228.3)''.

16–A. A new subsection 702.170–17 is added reading as follows: 702.170–17 Automated Directives System. *Automated Directives System (''ADS'')* means USAID's system of internal directives, regulations, and procedures.

References to ''ADS'' throughout this chapter 7 are references to the Automated Directives System. Procurement-related sections of this system are accessible to the general public at internet address: http://www.info.usaid.gov/ftp__data/pub/handbooks/index.html. The entire ADS is available on the Directives Resource Compact Disk (DR–CD), which may be purchased from the Agency at cost by submitting a completed DR–CD order form. To request a fax copy of the DR–CD order form, send an e-mail with your fax number to DRC@USAID.GOV.

PART 703—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

17. A new section 703.104–11 is added to read as follows;

703.104–11 Processing violations or possible violations.

The individual to whom the contracting officer should forward information and documentation as required in FAR 3.104–10 is the contracting officer's supervisor.

703.4 [Removed]

18. Subpart 703.4 is removed.

PART 704—ADMINISTRATION MATTERS

704.404 [Amended]

19. Section 704.404 is amended by revising ''Limited Official Use'' to read ''Sensitive But Unclassified''.

704.803 [Removed]

20. Section 704.803 is removed and Subpart 704.8 is reserved (the subpart heading is retained).

PART 705—PUBLICIZING CONTRACT ACTIONS

705.002 [Amended]

21. Section 705.002 is amended by designating the existing text as paragraph (a) and by adding the following paragraph (b):

705.002 Policy.

* * * * *

(b) USAID policy is to include all Commerce Business Daily Notices and solicitations on the Internet.

705.207 [Amended]

22. Section 705.207 is amended in paragraph (a) by revising ''made available for development assistance or for assistance for famine recovery and development in Africa'' to read ''referred to in section 706.302–71(a)'', and by removing ''726.104'' in the last sentence of the section and inserting in its place ''726.7005''.

PART 706—COMPETITIVE REQUIREMENTS

706.302–5 [Amended]

23. Section 706.302–5 is amended by adding ''Certain'' to the beginning of the first sentence.

706.302–70 [Revised]

24. Paragraph (c)(4) of section 706.302–70 is revised to read as follows:

706.302–70 Impariment of foreign aid programs.

* * * * *

(c) * * *

(4) Use of the authority in 706.302–70(b)(5) for proposed follow-on amendments in excess of one year or over $250,000 is subject to the approval of the Agency Competition Advocate. For all other follow-on amendments using this authority, the contracting officer's certification required in FAR 6.303–2(a)(12) will serve as approval.

706.302–71 [Amended]

25. Section 706.302–71 is amended by removing ''(2)'' after ''in paragraph (a)'' in paragraph (b)(1) and by revising paragraph (a) to read as follows:

706.302–71 Small disadvantaged businesses.

(a) *Authority.* (1) Citations: Sec. 579, Pub. L. 101–167 (Fiscal year (FY) 1990), Sec. 567, Pub. L. 101–513 (FY 1991), Sec. 567, Pub. L. 102–145 (FY 1992), Sec. 562, Pub. L. 102–391 (FY 1993), Sec. 558, Pub. L. 103–87 (FY 1994), and Sec. 555, Pub. L. 103–306 (FY 1995).

(2) Except to the extend otherwise determined by the Administrator, not less than ten percent of amounts made available through the appropriations cited in paragraph (a)(1) of this section for development assistance and for assistance for famine recovery and development in Africa shall be used only for activities of disadvantaged enterprises (as defined in 726.7002). In order to achieve this goal, USAID is authorized in the cited statutes to use other than full and open competition to award contracts to small business concerns owned and controlled by socially and economically disadvantaged individuals (small disadvantaged businesses as defined in 726.7002), historically black colleges and universities, colleges and universities having a student body of which more than 40 percent of the students are Hispanic Americans, and private voluntary organizations which are controlled by individuals who are socially and economically disadvantaged, as the terms are defined in 726.7002.

* * * * *

PART 708—REQUIRED SOURCES OF SUPPLIES AND SERVICES

PART 708—[REMOVED]

26. Part 708 is removed.

PART 708—CONTRACTOR QUALIFICATIONS

709.402 [Removed]

27. Section 709.402 is removed.

28. A new section 709.403 is added to read as follows:

709.403 Definitions.

Debarring official in USAID is the Procurement Executive.

Suspending official in USAID is the Procurement Executive.

709.503 [Amended]

29. The first sentence of section 709.503 is amended by revising ''(AIDR 702.170–13(c)(4)'' to read ''((48 CFR) AIDAR 702.170–13(c)(4))''.

PART 711—DESCRIBING AGENCY NEEDS

711.022–70 [Redesignated and amended]

30. Section 711.022–70 is amended by redesignating it as 711.002–70; by revising ''(M/AS)'' in paragraph (b)(1) to read ''(as designated in ADS chapter 323)''; and by removing ''(M/AS)'' from paragraph (b)(3).

PART 715—CONTRACTING BY NEGOTIATION

715.415 [Amended]

31. Section 715.413–22 amended by removing paragraph (c) introductory left; by removing paragraph (2) at the end of the section; and by revising paragraph (b) to read as follows:

715.413–2 Alternate II

* * * * *

(b) Prior to releasing proposals outside the Government for evaluation, the contracting officer shall obtain a signed and dated copy of a certification and agreement from each NGE and EAC substantially as follows:

* * * * *

715.613–71 [Amended]

32. Section 715.613–71 is amended by removing paragraphs (d) and (e), by redesignating paragraph (f) as paragraph (d), by revising ''(b)(1)'' in newly-designated (d)(3)(i) to read ''(c)'', by revising ''request for expression of interest'' and ''project'' in the second sentence of newly-designated (d)(4) to

read ''REI'' and ''activity'', respectively, and by revising paragraphs (a), (b), and (c) to read as follows:

715.613–71 Title XII selection procedure—collaborative assistance.

(a) *General.* (48 CFR) AIDAR 706.302–70(b)(4) provides authority for other than full and open competition when selecting Title XII institutions to perform Title XII activities.

(b) *Scope of subsection.* This subsection prescribes policies and procedures for the selection of institutions eligible under Title XII of the Foreign Assistance Act of 1961, as amended, to perform activities authorized under Title XII, where USAID has determined, in accordance with paragraph (c) of this subsection, that use of the collaborative assistance contracting system is appropriate. See AIDAR Appendix F (of this chapter)—Use of Collaborative Assistance Method for Title XII Activities for a more complete definition and discussion of the collaborative assistance method.

(c) *Determinations.* The following findings and determinations must be made prior to initiating any contract actions under the collaborative assistance method:

(1) The cognizant technical office makes a preliminary finding that:

(i) An activity is authorized by Title XII; and

(ii) Should be classed as collaborative assistance because a continuing collaborative relationship between USAID, the host country, and the contractor is required from design through completion of the activity, and USAID, host country, and contractor participation in a continuing review and evaluation of the activity is essential for its proper execution.

(2) Based upon this preliminary finding, the cognizant technical office shall establish an evaluation panel consisting of a representative of the contracting officer, and any other representatives considered appropriate by the chairman to review the proposed activity for its appropriateness under the collaborative assistance method.

(3) If supported by the panel's findings, the chairman will make a formal, written determination that the collaborative assistance method is the appropriate contracting method for the Title XII activity in question.

* * * * *

PART 719—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

719.270 [Amended]

33. Section 719.270 is amended by removing ''[FAR 13.101 and 13.103(b)]'' from paragraph (d) and by removing paragraph (k).

719.271–2 [Amended]

34. Paragraph (b)(8) of section 719.271–2 is amended by removing ''[FAR 13.101 and 13.103(b)]''.

719.271–3 [Amended]

35. Paragraph (j) of section 719.271–3 is amended by adding ''to'' between the third comma and ''SDB''.

719.271–6 [Amended]

36. Paragraph (a) introductory text of section 719.271–6 is amended by removing ''(FAR 13.101 and 13.103(b))'' and ''and AIDAR Appendix F'' is removed from paragraph (a)(3).

PART 722—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITION

722.805–70 [Amended]

37. At the end of paragraph (d)(3) in section 722.805–70, remove ''(see 704.803(a))''.

PART 725—FOREIGN ACQUISITION

725.701 [Amended]

38. Section 725.701 is revised to read as follows:

725.701 General

USAID's source, origin and nationality requirements for program-funded contracts and subcontracts are established in 22 CFR part 228, Rules on Source, Origin and Nationality for Commodities and Services Financed by USAID. These policies as they apply to subcontracts and purchases under USAID program-funded contracts have been incorporated into the contract clauses referenced in 725.704 and 725.705 of this subpart.

725.704 [Revised]

39. Section 725.704 is revised to read as follows:

725.704 Source, origin and nationality requirements—Contract clause.

The clause in 752.225–70 is required in all USAID program-funded solicitations and in all program-funded contracts under which the contractor may procure goods or services.

725.705 [Revised]

40. Section 725.705 is revised to read as follows:

725.705 Local procurement—contract clause.

Local procurement may be undertaken in accordance with the provisions of 22 CFR 228.40. All contracts involving performance overseas shall contain the clause in 752.225–71.

725.706 [Amended]

41. Section 725.706 paragraph (a) is revised to read as follows:

725.706 Geographic source waivers.

(a) Authority to waive source, origin, nationality, and transportation services requirements is set forth in Chapters 103 and 310 of the ADS

* * * * *

PART 726—OTHER SOCIOECONOMIC PROGRAMS

726.7001 [Amended]

42. Section 726.7001 is amended by revising the second ''the'' in the first sentence to read ''certain'', and by adding ''(see section 706.302–71(a))'' between ''acts'' and ''concerning'' in the same sentence.

726.7003 [Amended]

43. Section 726.7003 is amended by revising ''for development assistance and for famine recovery and development in Africa'' in the introductory paragraph to read ''from the appropriations cited in section 706.302–71(a)(1)'', and in paragraph (c) by revising ''subpart 726.3'' to read ''section 726.7007''.

726.7005 [Amended]

44. Section 726.7005 is amended by revising ''726.301'' in the first sentence to read ''726.7007'' and by revising ''726.301(b)'' in the last sentence to read ''726.7007''.

726.7006 [Amended]

45. Section 726.7006 is amended by revising ''726.101'' in the first sentence of paragraph (a) to read ''726.7002''.

726.7007 [Amended]

46. In section 726.7007, paragraph (a) is amended by revising ''726.101'' to read ''726.7002'' and by revising ''for development assistance or for assistance for famine recovery and development in Africa'' to read ''from the appropriations cited in section 706.302–71(a)(1)''; paragraph (b) is amended by revising ''726.104'' to read ''716.7005''.

PART 731—CONTRACT COST PRINCIPLES AND PROCEDURES

731.205–6 [Amended]

47. Section 731.205–6 is amended by revising the parenthetical sentence in paragraph (d) to read ''The Contracting Officer shall only provide such approval after internal Agency procedures for review/approval of salaries in excess of the ES–6 rate have been followed.''

731.371 [Amended]

48. Paragraph (b)(1) of section 731.371 is amended by removing the second sentence and inserting in its place ''The Contracting Officer shall only provide such approval after internal Agency procedures for review/approval of salaries in excess of the ES–6 rate have been followed.''

PART 732—CONTRACT FINANCING

732.401 [Amended]

49. Paragraph (a) of section 732.401 is amended by revising ''May 12, 1955'' to read ''May 12, 1965''.

PART 733—PROTESTS, DISPUTES AND APPEALS

733.270–2 [Amended]

50. Section 733.270–2 is amended by removing the ''s'' at the end of the word ''furnishings'' in the second sentence of paragraph (e).

PART 750—EXTRAORDINARY CONTRACTUAL ACTIONS

750.7101 [Amended]

51. Paragraph (a) of section 750.7101 is amended by capitalizing ''agency'' in ''International Development Cooperation agency Delegation of Authority'' in the middle of the first sentence.

750.7109–3 [Amended]

52. Section 750.7109–3 is amended by revising ''dsecribed'' to read ''described''.

750.7110 [Amended]

53. Section 750.7110 and subsections 750.7110–1 through 750.7110–5 are revised as follows:

750.7110 Processing cases.

750.7110–1 Investigation.

The Evaluation Division of the Office of Procurement (M/OP/E) shall be responsible for assuring that the case prepared by the cognizant contracting officer makes a thorough investigation of all facts and issues relevant to each situation. Facts and evidence shall be obtained from contractor and Government personnel and shall include signed statements of material facts within the knowledge of the individuals where documentary evidence is lacking and audits where considered necessary to establish financial or cost related facts. The investigation shall establish the facts essential to meet the standards for deciding the particular case and shall address the limitations upon exercise of the Procurement Executive's authority to approve the request.

750.7110–2 Office of General Counsel coordination.

Prior to the submission of a case to the Procurement Executive recommending extraordinary contractual relief, the claim shall be fully developed by the cognizant contracting officer and concurrences or comments shall be obtained from the Office of General Counsel for the proposed relief to be granted. Such concurrences or comments shall be incorporated in or accompany the action memorandum submitted for consideration to the Procurement Executive in accordance with 750.7110–3.

750.7110–3 Submission of cases to the Procurement Executive.

Cases to be submitted for consideration by the Procurement Executive shall be prepared and forwarded by the cognizant contracting officer through M/OP/E to the Procurement Executive by means of an action memorandum. M/OP/E will review the action memorandum for accuracy and completeness. The action memorandum shall provide for approval or disapproval by the Procurement Executive of the disposition recommended by the contracting officer. The action memorandum shall address:

(a) The nature of the case;

(b) The basis for authority to act under section 750.7101;

(c) The findings of fact essential to the case (see 750.7109–3) arranged chronologically with cross references to supporting enclosures;

(d) The conclusions drawn from applying the standards for deciding cases, as set forth in 750.7106, to the findings of fact;

(e) Compliance with the limitations upon exercise of authority, as set forth in section 750.7107 (for informal commitments, include statements addressing each of the limitations in paragraph (d) of 750.7107):

(f) Concurrences or comments obtained from the Office of General Counsel;

(g) Verification of funds availability and the contracting officer's determination of cost/price reasonableness when the disposition recommended requires payment to a contractor;

(h) The disposition recommended and, if contractual action is recommended with respect to cases falling within Section 4 of the Executive Order, the opinion of the contracting officer that such action is necessary to protect the foreign policy interest of the United States; and

(i) The action memorandum shall enclose all evidentiary materials, including the reports and comments of all cognizant Government or other officials, and a copy of the contractor's request. The action memorandum should provide the following information related to the contractor's request, as applicable:

(1) Date of request;

(2) Date request received by USAID:

(3) Contract number;

(4) Contractor's name and address;

(5) Name, address, and phone number of contractor's representative;

(6) Name, office symbol, and phone number of cognizant contracting officer;

(7) Amount of request.

750.7110–4 Processing by Procurement Executive.

When the action memorandum has been determined to be as accurate and complete as possible and has been prepared in accordance with this subpart, M/OP/E will forward the action memorandum to the Procurement Executive. The Procurement Executive will sign and date the action memorandum indicating approval or disapproval of the disposition recommended by the contracting officer.

750.7110–5 Contract files.

The fully executed action memorandum indicating approval/disapproval and a copy of the contractual document implementing any approval contractual action shall be placed in the contract file.

PART 752—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

752.200 [Amended]

54. The first sentence of section 752.200 is corrected by adding an ''s'' to the end of ''contract''.

752.204–2 [Amended]

55. Section 752.204–2 is amended by revising ''Volume 5, Foreign Affairs Manual, Chapter 900'' to read ''Volume 12, Foreign Affairs Manual, Chapter 540'', and by revising ''Limited Official use'' wherever it appears to read ''Sensitive But Unclassified''.

752.209–70 [Removed]

56. Section 752.209–70 is removed.

752.219–8 [Amended]

57. Section 752.219–8 is amended by revising ''FAR 19.7008(a)'' in the second sentence to read ''FAR 19.708(a)'', by removing ''in FAR 13.000'' in the introductory text of the clause after ''simplified acquisition threshold'', and by removing the quotation mark at the end of the section.

752.225–9 [Amended]

58. Section 752.225–9 is amended by revising ''subpart'' at the end of the first sentence to read ''chapter'', and by revising ''752.7004'' to read ''752.225–70'' in the last sentence.

59. New section 752.225–70 is added as follows:

752.225–70 Source, origin and nationality requirements.

The following clause is required as prescribed in 725.704.

Source, Origin and Nationality Requirements (May 1997)

(a) Except as may be specifically approved by the Contracting Officer, all commodities (e.g., equipment, materials, vehicles, supplies) and services (including commodity transportation services) which will be financed under this contract with U.S. dollars shall be procured in accordance with the requirements in 22 CFR part 228, ''Rules on Source, Origin and Nationality for Commodities and Services Financed by USAID.'' The authorized source for procurement is Geographic Code 000 unless otherwise specified in the schedule of this contract. Guidance on eligibility of specific goods or services may be obtained from the Contracting Officer.

(b) Ineligible goods and services. The Contractor shall not procure any of the following goods or services under this contract:

(1) Military equipment,

(2) Surveillance equipment,

(3) Commodities and services for support of police and other law enforcement activities,

(4) Abortion equipment and services,

(5) Luxury goods and gambling equipment, or

(6) Weather modification equipment.

(c) Restricted goods. The Contractor shall not procure any of the following goods or services without the prior written approval of the Contracting Officer:

(1) Agricultural commodities,

(2) Motor vehicles,

(3) Pharmaceuticals and contraceptive items,

(4) Pesticides,

(5) Fertilizer,

(6) Used equipment, or

(7) U.S. government-owned excess property.

If USAID determines that the Contractor has procured any of these specific restricted goods under this contract without the prior written authorization of the Contracting Officer, and has received payment for such purposes, the Contractor agrees to refund to USAID the entire amount of the purchase.

60. New Section 752.225–71 is added to read as follows:

752.225–71 Local procurement.

For use in any USAID contract involving performance overseas.

Local Procurement (May 1997)

(a) Local procurement involves the use of appropriated funds to finance the procurement of goods and services supplied by local businesses, dealers or producers, with payment normally being in the currency of the cooperating country.

(b) All locally-financed procurements must be covered by source/origin and nationality waivers as set forth in subpart F of 22 CFR part 238 except as provided for in 22 CFR 228.40, Local procurement.

752.226–1 [Amended]

61. Section 752.226–1 is amended by revising ''726.201'' in the introductory paragraph to read ''726.7006(a)''.

752.226–2 [Amended]

62.Section 752.226–2 is amended by revising ''726.301'' in the introductory paragraph to read ''726.7007'', by revising the date of the clause ''(April 1991)'' to read ''(April 1997)'', and by removing the second sentence of paragraph (c)(3).

752.226–3 [Amended]

63. Section 752.226–3 is amended by revising ''726.302'' in the introductory paragraph to read ''726.7008''.

752.228–7 [Amended]

64. Section 752.228–7 is amended by revising the last sentence to read as follows:

752.228–7 Insurance—liability to third persons.

* * * * *

( ) *Insurance on private automobiles.* * * * Copies of such insurance policies shall be preserved and made available as part of the Contractor's records which are required to be preserved and made available by the ''Audit and Records—Negotiation'' clause of this contract.

752.245–70 [Amended]

65. Section 752.245–70 is amended by adding'', except for those for commercial items,'' between ''contracts'' and ''must'' in the introductory paragraph, by revising ''AID-Contractor'' to read ''USAID-Contractor'' in item B.2.b. in the form entitled ''Annual Report of Government Property in Contractor's Custody'', and by revising ''or'' to read ''for'' in the second attestation in the paragraph entitled ''Property Inventory Verifications''.

752.245–71 [Amended]

66. The introductory text of section 752.245–71 is revised to read as follows:

752.245–71 Title to and care of property.

The following clause shall be included in all non-commercial contracts when the contractor will acquire property under the contract for use overseas and the property will be titled to the Cooperating Country.

* * * * *

752.7001 [Revised]

67. Section 752.7001 is revised to read as follows:

752.7001 Biographical data.

The following clause is to be included in all USAID cost reimbursement contracts.

Biographical Data (May 1997)

The Contractor agrees to furnish to the Contracting Officer and AID Form 1420–17, ''Contractor Employee Biographical Data Sheet'', biographical information on the following individuals to be employed in the performance of the contract: (1) All individuals to be sent outside of the United States, or (2) any employees designated as ''key personnel''. Biographical data in the form usually maintained by the Contractor on the other individuals employed under the contract shall be available for review by USAID at the Contractor's headquarters. A supply of AID Form 1420–17 will be provided with this contract. The Contractor may reproduce additional copies as necessary.

752.7004 [Revised]

68. Section 752.7004 is revised to read as follows.

752.7004 Emergency locator information.

The following clause is required to be included in all contracts requiring travel overseas.

Emergency Locator Information (May 1997)

The Contractor agrees to provide the following information to the Mission Administrative Officer on or before the arrival in the host country of every contract employee or dependent:

(1) The individual's full name, home address, and telephone number.

(2) The name and number of the contract, and whether the individual is an employee or dependent.

(3) The contractor's name, home office address, and telephone number, including any after-hours emergency number(s), and the name of the contractor's home office staff member having administrative responsibility for the contract.

(4) The name, address, and telephone number(s) of each individual's next of kin.

(5) Any special instructions pertaining to emergency situations such as power of attorney designees or alternate contact persons.

752.7007 [Amended]

69. Section 752.7007 is amended by adding '', as prescribed in 731.205–6(d) or 731.371(b), as applicable'' after ''Contracting Officer'' in paragraph (b).

752.7008 [Amended]

70. The introductory paragraph in section 752.7008 is amended by adding ''non-commercial'' before the word ''contracts''.

752.7010 [Amended]

71. The introductory paragraph in section 752.7010 is amended by adding

''non-commercial'' before the word ''contracts''.

752.7015 [Amended]

72. Section 752.7015 is amended by revising the introductory paragraph, the clause heading, paragraph (a)(2), and paragraph (a)(4) of the clause to read as follows:

752.7015 Use of pouch facilities.

For use in all USAID non-commercial contracts exceeding the simplified acquisition threshold and involving performance overseas.

Use of Pouch Facilities (April 1996)

(a) * * *

(2) U.S. citizen employees of U.S. contractors are authorized use of the pouch for personal mail up to a maximum of one pound per shipment (but see paragraph (a)(3) of this clause).

* * * * *

(4) Official mail as authorized by paragraph (a)(1) of this clause should be addressed as follows: Individual or Organization name, followed by the symbol ''C'', city Name of Post, U.S. Agency for International Development, Washington, DC 20523–0001.

* * * * *

752.7017 [Removed]

73. Section 752.7017 is removed and reserved.

752.7027 [Amended]

74. Section 752.7027 is amended by adding ''services'' before the word ''contracts'' in the first sentence of the introductory paragraph and by revising ''or'' to read ''of'' in the heading of paragraph (c) of the clause.

752.7029 [Amended]

75. Section 752.7029 is amended by adding ''non-commercial'' before the word ''contracts'' in the introductory paragraph.

752.7033 [Amended]

76. Section 752.7033 is amended by revising '', and assigned Control No. 0412–0356'' in the second sentence of paragraph (b) to read ''(see 701.105(a))'', and by revising the clause heading and paragraph (a) to read as follows:

752.7033 Physical Fitness.

* * * * *

Physical Fitness (May 1997)

* * * * *

(a) *Assignments of less than 60 days in the Cooperating Country.* The contractor shall require employees being assigned to the Cooperating Country for less than 60 days to be examined by a licensed doctor of medicine. The contractor shall require the doctor to provide to the contractor a written statement that in his/her medical opinion, the employee is physically qualified to engage in the type of activity for which he/she is employed and the employee is physically able to reside in the country to which he/she is assigned. Under a cost reimbursement contract, if the contractor has no written statement of medical opinion on file prior to the departure for the Cooperating Country of any employee and such employee is unable to perform the type of activity for which he/she is employed or cannot complete his/her tour of duty because of any physical disability (other than physical disability arising from an accident while employed under this contract), the contractor shall be responsible for returning the disabled employee to his/her point of hire and providing a replacement at no additional cost to the Government. In addition, in the case of a cost reimbursement contract, the contractor shall not be entitled to reimbursement for any additional costs attributable to delays or other circumstances caused by the employee's inability to complete his/her tour of duty.

* * * * *

PART 753—FORMS

753.107 [Amended]

77. Section 753.107 is amended by revising ''M/AS/PP/PP'' to read ''M/AS/ISS''.

78. Chapter 7 is amended by removing Appendices A, C, G, and H and reserving each.

Dated: May 13, 1997.

Marcus L. Stevenson,

Procurement Executive.

[FR Doc. 97–18603 Filed 7–28–97; 8:45 am]

BILLING CODE 6116–01–M

DEPARTMENT OF DEFENSE

48 CFR Parts 204, 215, 216, 232, 239, and 252

[DFARS Case 95–D708]

Defense Federal Acquisition Regulations Supplement; Truth in Negotiations and Related Changes

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Director of Defense Procurement has issued a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to conform to amendments to the Federal Acquisition Regulation (FAR) pertaining to cost or pricing data requirements.

EFFECTIVE DATE: July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, PDUSD (A&T) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–0131; telefax (703) 602–1031.

SUPPLEMENTARY INFORMATION:

A. Background

A proposed rule was published in the **Federal Register** on October 23, 1995 (60 FR 54326). The rule proposed amendments to the DFARS to conform to FAR amendments that implemented requirements of the Federal Acquisition Streamlining Act of 1994 (FASA) (Public Law 103–355) pertaining to the submission of cost or pricing data by offerors and contractors. The rule also proposed to remove DFARS language pertaining to work measurement systems, as Section 2201(b) of FASA repealed 10 U.S.C. 2406, the primary statute covering work measurement systems.

Additional changes in the final rule include—

- Removal of the proposed language at DFARS 215.804–1(b)(1)(B)(*3*) to conform to FAR standards for adequate price competition.
- Amendments to DFARS 216.203–4–70 and the clauses at 252.216–7000 and 252.216–7001 to remove obsolete FAR references.
- Amendments to DFARS Part 239 and removal of the clauses at 252.239–7009 and 252.239–7010 to eliminate special cost or pricing data and audit requirements for telecommunications services.
- Retention of the clause at DFARS 252.215–7000, as the clause is considered to be a useful supplementation of the clauses at FAR 52.215–23, 52.215–24, and 52.215–25.

Public comments were received from four respondents. All comments were considered in the development of the final rule.

B. Regulatory Flexibility Act

DoD certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* because the rule primarily consists of conforming DFARS amendments to reflect existing FAR requirements for submission of cost or pricing data, and because most prime contracts, as well as subcontracts, with small businesses do not require the submission of cost or pricing data.

C. Paperwork Reduction Act

This rule does not add any new information collection requirements that require approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.* However, it is estimated that elimination of the clause at 252.239–7009 will reduce annual paperwork burden requirements by

4,400 hours (previously approved under OMB Clearance 0704–0187).

List of Subjects in 48 CFR Parts 204, 215, 216, 232, 239, and 252

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR Parts 204, 215, 216, 232, 239, and 252 are amended as follows:

1. The authority citation for 48 CFR Parts 204, 215, 216, 232, 239, and 252 continues to read as follows:

A**uthority:** 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 204—ADMINISTRATIVE MATTERS

204.805 [Amended]

2. Section 204.805 is amended in the first sentence of paragraph (5) by removing the words ''certification of''.

PART 215—CONTRACTING BY NEGOTIATION

215.801 [Removed]

3. Section 215.801 is removed.

4. Sections 215.804 and 215.804–1 are revised to read as follows:

215.804 Cost or pricing data and information other than cost or pricing data.

215.804–1 Prohibition on obtaining cost or pricing data.

(b) *Standards for exceptions from cost or pricing data requirements.* (1) *Adequate price competition.* (A) An example of a price ''based on'' adequate price competition is exercise of a priced option in a contract where adequate price competition existed, if the contracting officer has determined that the option price is reasonable in accordance with FAR 17.207(d);

(B) Dual or multiple source programs.

(1) In dual or multiple source programs, the determination of adequate price competition must be made on a case-by-case basis. Contracting officers must exercise deliberation and thorough review in making the determination. Even when adequate price competition exists, in certain cases it may be appropriate to obtain additional information to assist in price analysis.

(2) Adequate price competition normally exists when—

(i) Prices are solicited across a full range of step quantities, normally including a 0–100 percent split, from at least two offerors that are individually capable of producing the full quantity; and

(ii) The reasonableness of all prices awarded is clearly established on the basis of price analysis (see FAR 15.805–2).

(4) *Exceptional cases.*

(A) The DoD has exempted the Canadian Commercial Corporation and its subcontractors from submission and certification of cost or pricing data on all acquisitions.

(B) The DoD has waived certain cost or pricing data requirements for nonprofit organizations (including educational institutions) on cost-reimbursement-no-fee contracts. The contracting officer shall require—

(1) Submission of information other than cost or pricing data to the extent necessary to determine price reasonableness and cost realism; and

(2) Cost or pricing data from subcontractors that are not nonprofit organizations.

215.804–3 [Removed]

5. Section 215.804–3 is removed.

215.804–6 Amended]

6. Section 215.804–6 is amended by redesignating paragraphs (b)(2)(A) and (B) as paragraphs (b)(1)(A) and (B), respectively.

7. Section 215.05–5 is amended by revising paragraph (a)(1)(A) to read as follows:

215.805–5 Field pricing support.

(a)(1)(A) Contracting officers shall request field pricing reports for—

(1) Fixed-price proposals exceeding the cost or pricing data threshold at FAR 15.804–2(a)(1);

(2) Cost-type proposals exceeding the cost or pricing data threshold at FAR 15.804–2(a) (1) from offerors with significant estimating system deficiencies (see 215.811–70(a)(3) and (c)(2)(i); or

* * * * *

8. Section 215.805–70 is amended by revising paragraph (b) to read as follows:

215.805–70 Cost realism analysis.

* * * * *

(b) The contracting officer should determine what information other than cost or pricing data is necessary for the cost realism analysis during acquisition planning and development of the solicitation. Unless such information is already available from Government sources, the contracting officer will need to ask the offerors for it.

(1) Request only necessary data; and

(2) Do not request submission of cost or pricing data.

9. Section 215.811–70 is amended by revising paragraphs (b)(2), (g)(3)(ii), and (h) to read as follows:

215.811–70 Disclosure, maintenance, and review requirements.

* * * * *

(b) * * *

(2) A large business contractor is subject to estimating system disclosure, maintenance, and review requirements if—

(i) In its preceding fiscal year, the contractor received DoD prime contracts or subcontracts totaling $50 million or more for which cost or pricing data were required; or

(ii) In its preceding fiscal year, the contractor received DoD prime contracts or subcontracts totaling $10 million or more (but less than $50 million) for which cost or pricing data were required and the contracting officer, with concurrence or at the request of the administrative contracting officer, determines it to be in the best interest of the Government (e.g., significant estimating problems are believed to exist or the contractor's sales are predominantly Government).

* * * * *

(g) * * *

(3) * * *

(ii) Indicate a specific time or subsequent event by which the contractor will submit a supplemental proposal, including cost or pricing data, identifying the cost impact adjustment necessitated by the deficient estimating system;

* * * * *

(h) *Contract clause.* Use the clause at 252.215–7002, Cost Estimating System Requirements, in all solicitations and contracts to be awarded on the basis of cost or pricing data.

215.872 [Removed and Reserved]

10. Section 215.872 is removed and reserved.

215.872–1 through 215.872–4 [Removed]

11. Sections 215.872–1 through 215.872–4 are removed.

PART 216—TYPES OF CONTRACTS

216.203–4 [Amended]

12. Section 216.203–4 is amended in the first sentence of paragraph (d)(xvi) by revising the reference ''15.804–3'' to read ''15.804–1''.

13. Section 216.203–4–70 is amended by revising paragraph (a); by removing paragraphs (b)(4) and (b)(6), and by redesignating paragraphs (b)(5) and (b)(7) as paragraphs (b)(4) and (b)(5), respectively. The revised text reads as follows:

216.203–4–70 Additional clauses.

(a) *Price adjustment for basic steel, aluminum, brass, bronze, or copper mill products.*

(1) The price adjustment clause at 252.216–7000, Economic Price Adjustment—Basic Steel, Aluminum, Brass, Bronze, or Copper Mill Products, may be used in fixed-price supply contracts for basic steel, aluminum, brass, bronze, or copper mill products, such as sheets, plates, and bars, when an established catalog or market price exists for the particular product being acquired.

(2) The 10 percent figure in paragraph (d)(1) of the clause shall not be exceeded unless approval is obtained at a level above the contracting officer.

* * * * *

PART 232—CONTRACT FINANCING

14. Section 232.502–1–71 is amended by revising paragraph (b)(3) to read as follows:

232.502–1–71 Customary flexible progress payments.

* * * * *

(b) * * *

(3) Contractors who submit cost or pricing data, as defined in FAR 15.801, for negotiated fixed-price contracts in excess of $1 million may request flexible progress payments.

* * * * *

PART 239—ACQUISITION OF INFORMATION TECHNOLOGY

15. Section 239.7406 is revised to read as follows:

239.7406 Cost or pricing data and information other than cost or pricing data.

(a) Common carriers are not required to submit cost or pricing data before award of contracts for tariffed services. Rates or preliminary estimates quoted by a common carrier for tariffed telecommunications services are considered to be prices set by regulation within the provisions of 10 U.S.C. 2306a. This is true even if the tariff is set after execution of the contract.

(b) Rates or preliminary estimates quoted by a common carrier for nontariffed telecommunications services or by a noncommon carrier for any telecommunications service are not considered prices set by law or regulation.

(c) Contracting officers shall obtain sufficient information to determine that the prices are reasonable. For example, cost or pricing data, if required in accordance with FAR 15.804–2, or information other than cost or pricing data, if required in accordance with FAR 15.804–5, may be necessary to support the reasonableness of—

(1) Nontariffed services;

(2) Special rates and charges not included in a tariff, whether filed or to be filed;

(3) Special assembly rates and charges;

(4) Special construction and equipment charges;

(5) Contingent liabilities that are fixed at the outset of the service;

(6) Proposed cancellation and termination charges under the clause at 252.239–7007, Cancellation or Termination of Orders—Common Carriers, and reuse arrangements under the clause at 252.239–7008, Reuse Arrangements;

(7) Rates contained in voluntary tariffs filed by nondominant common carriers; or

(8) A tariff, whether filed or to be filed, for new services installed or developed primarily for Government use.

239.7411 [Amended]

16. Section 239.7411 is amended by removing paragraphs (a)(8) and (a)(9); and in paragraph (a)(7) by removing the semicolon and inserting a period in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.215–7000 [Amended]

17. Section 252.215–7000 is amended in the introductory text by revising the reference ''215.804–8(1)'' to read ''215.804–8''.

252.215–7002 [Amended]

18. Section 252.215–7002 is amended by revising the clause date to read ''(JUL 1997)''; and in paragraphs (c)(1) and (c)(2)(i) by removing the word ''certified''.

19. Section 252.216–7000 is amended by revising the clause date and paragraph (a) to read as follows:

252.216–7000 Economic Price Adjustment—Basic Steel, Aluminum, Brass, Bronze, or Copper Mill Products.

* * * * *

Economic Price Adjustment-Basic Steel, Aluminum, Brass, Bronze, or Copper Mill Products (Jul 1997)

(a) *Definitions.*

As used in this clause—

Established price means a price which is an established catalog or market price for a commercial item sold in substantial quantities to the general public.

Unit price excludes any part of the price which reflects requirements for preservation, packaging, and packing beyond standard commercial practice.

* * * * *

20. Section 252.216–7001 is amended by revising the clause date; and in paragraph (a) by revising the definition of ''Established price'' to read as follows:

252.216–7001 Economic Price Adjustment—Nonstandard Steel Items.

* * * * *

Economic Price Adjustment—Nonstandard Steel Items (Jul 1997)

(a) * * *

Established price is—

(1) A price which is an established catalog or market price of a commercial item sold in substantial quantities to the general public; and

(2) The net price after applying any applicable standard trade discounts offered by the Contractor from its catalog, list, or schedule price. (But see Note 6.)

* * * * *

§ 252.239–7006 [Amended]

21. Section 252.239–7006 is amended by revising the clause date to read ''(Jul 1997)''; and in paragraph (a)(2) by inserting a comma after the words ''Before filing.''

§§ 252.239–7009 and 252.239–7010 [Removed and Reserved]

22. Sections 252.239–7009 and 252.239–7010 are removed and reserved.

23. Section 252.243–7000 is amended by revising the clause date and paragraph (c) to read as follows:

§ 252.243–7000 Engineering Change Proposals.

* * * * *

Engineering Change Proposals (Jul 1997)

* * * * *

(c) When the price** of the engineering change is $500,000 or more, the Contractor shall submit—

(1) A completed SF 1411, Contract Pricing Proposal Cover Sheet (Cost or Pricing Data Required); and

(2) At the time of agreement on price*, or on another date agreed upon between the parties, a signed Certificate of Current Cost or Pricing Data.

* * * * *

[FR Doc. 97–19907 Filed 7–28–97; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 961126334–7052–02; I.D. 072297E]

Fisheries of the Exclusive Economic Zone Off Alaska; Northern Rockfish in the Eastern Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is prohibiting retention of northern rockfish in the Eastern Regulatory Area of the Gulf of Alaska (GOA). NMFS is requiring that catches of northern rockfish in this area be treated in the same manner as prohibited species and discarded at sea with a minimum of injury. This action is necessary because the northern rockfish 1997 total allowable catch (TAC) in this area has been reached.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 23, 1997, until 2400 hrs, A.l.t., December 31, 1997.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by NMFS according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 1997 TAC of northern rockfish in the Eastern Regulatory Area of the GOA was established by the Final 1997 Harvest Specifications of Groundfish for the GOA (62 FR 8179, February 24, 1997) as 10 metric tons (mt). See § 679.20(c)(3)(ii).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS, has determined that the 1997 TAC for northern rockfish in the Eastern Regulatory Area of the GOA has been reached. Therefore, NMFS is requiring that further catches of northern rockfish in the Eastern Regulatory Area of the GOA be treated as prohibited species in accordance with § 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. It must be implemented immediately to prevent overharvesting the 1997 TAC for northern rockfish in the Eastern Regulatory Area of the GOA. Providing an opportunity for prior notice and comment would be impracticable and contrary to public interest. The fleet has already taken the directed fishing allowance for northern rockfish. Further delay would only result in overharvest and disrupt the FMP's objective of allowing incidental catch to be retained throughout the year. NMFS finds for good cause that the implementation of this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by Sec. 679.20 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 23, 1997.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 97–19846 Filed 7–24–97; 9:56 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 550

RIN 3206–AF38

Pay Administration (General); Lump-Sum Payments for Annual Leave

AGENCY: Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing proposed regulations to establish a Governmentwide policy for calculating lump-sum payments for accumulated and accrued annual leave for employees who separate from the Federal service.

DATES: Comments must be received on or before September 29, 1997.

ADDRESSES: Comments may be sent or delivered to Donald J. Winstead, Assistant Director for Compensation Policy, Human Resources Systems Service, Office of Personnel Management, Room 6H31, 1900 E Street NW., Washington, DC 20415 (FAX: (202) 606–0824), or email at payleave@opm.gov.

FOR FURTHER INFORMATION CONTACT: Brenda Roberts, (202) 606–2858, FAX (202) 606–0824, or email at payleave@opm.gov.

SUPPLEMENTARY INFORMATION: The Technical and Miscellaneous Civil Service Amendments Act of 1992 (Pub. L. 102–378, October 2, 1992) added section 5553 to title 5, United States Code, to give the Office of Personnel Management regulatory authority for the administration of lump-sum payments for accumulated and accrued annual leave. Under 5 U.S.C. 5551 and 5552, such lump-sum payments are made when an employee (1) separates from the Federal service or (2) enters on active duty in the armed forces and elects to receive a lump-sum payment for accumulated and accrued annual leave. The lump-sum payment must equal the pay the employee would have received had he or she remained employed until expiration of the period of annual leave.

Section 6306 of title 5, United States Code, provides that when an employee is reemployed in the Federal service prior to the expiration of the lump-sum period, he or she must refund an amount equal to the pay covering the period between the date of reemployment and the expiration of the lump-sum period. In addition, an amount of annual leave equal to the days or hours of work remaining between the date of reemployment and the expiration of the lump-sum leave period is recredited to the employee. OPM is authorized to regulate this requirement by 5 U.S.C. 6311.

OPM recognizes that agencies currently calculate lump-sum payments for annual leave and refunds based on their interpretation of the broad statutory language in 5 U.S.C. 5551, 5552, and 6306; OPM's regulations on lump-sum payments for employees who receive nonforeign area cost-of-living allowances, post differentials, or availability pay; and additional guidance provided by the former Federal Personnel Manual, Comptroller General opinions, court decisions, and the Federal Wage System Operating Manual. Consequently, agencies may not have consistent policies for including some types of pay in lump-sum payments for annual leave. On March 3, 1995, OPM asked Directors of Personnel for assistance in developing proposed regulations on lump-sum payments for annual leave. We received comments from 30 agencies. Agency opinions varied widely on what types of pay should be included in or excluded from lump-sum payments. After careful consideration of all agency comments, we are proposing Governmentwide rules for determining how lump-sum payments should be calculated. The proposed regulations are designed to ensure that lump-sum payments are calculated consistently throughout the Federal Government. When OPM issues final regulations on lump-sum payments for annual leave, they will not be made retroactive. The final regulations will apply only to lump-sum payments made by an agency on or after the effective date of the final regulations. The following paragraphs summarize the major provisions of the proposed regulations.

Employees Eligible for a Lump-Sum Payment

Generally, an employee is entitled to a lump-sum payment for accumulated and accrued annual leave when he or she (1) separates or retires from Federal service; (2) dies; or (3) transfers to a position that is not covered by subchapter I of chapter 63 of title 5, United States Code, or to a position that is covered by a different leave system, when his or her accumulated and accrued annual leave cannot be transferred. In addition, section 1611 of Pub. L. 104–201, September 23, 1996, added paragraph (c) to 5 U.S.C. 5551 to require the Department of Defense (DOD) to pay a lump-sum payment to an employee for any unused annual leave that was restored under 5 U.S.C. 6304(d)(3) when the employee (1) transfers to a position in any other department or agency of the Federal Government or (2) moves to a position within DOD not located at an installation undergoing closure or realignment. This new entitlement to a lump-sum payment for certain DOD employees became effective on September 23, 1996.

There are five exceptions to the general rule that employees who separate, die, or transfer are entitled to a lump-sum payment:

(1) An employee who enters on active duty in the armed forces may elect to receive a lump-sum payment for accumulated and accrued annual leave or may request that the annual leave remain to his or her credit until he or she returns from active duty.

(2) An employee in a missing status (as defined in 5 U.S.C. 5561(5)) on or after January 1, 1965, is entitled to receive a lump-sum payment for accumulated and accrued annual leave upon return or may elect to have the annual leave restored in a separate leave account under 5 U.S.C. 6304(d)(2). The lump-sum payment is computed based on the pay in effect at the time the annual leave became subject to forfeiture.

(3) An employee who transfers to a position excepted from subchapter I of chapter 63 of title 5, United States Code, by 5 U.S.C. 6301(2)(x)-(xiii) (i.e., certain Presidential appointees or designees) may not receive a lump-sum payment upon appointment to the new position. The annual leave must be held in abeyance for recredit if the employee is

subsequently reemployed without a break in service in a position to which his or her annual leave may be transferred. If the employee does not return to a position to which his or her annual leave can be transferred and later becomes eligible for a lump-sum payment, the lump-sum payment is computed based on the pay in effect at the time the employee initially transferred to the excepted position. The lump-sum period is projected beginning on the effective date of the employee's separation, death, or transfer.

(4) An employee who transfers to a position not covered by the Federal leave system established under chapter 63 of title 5, United States Code, and to which only a portion of his or her annual leave may be transferred, will have the remaining annual leave held in abeyance for recredit until he or she is subsequently reemployed without a break in service in a position to which his or her annual leave may be transferred. If the employee does not return to a position to which his or her annual leave can be transferred and later becomes eligible for a lump-sum payment, the lump-sum payment is computed based on the rate in effect at the time the employee initially transferred to the position to which only a portion of his or her annual leave could be transferred. The lump-sum payment is paid by the current employing agency. The lump-sum period is projected beginning on the effective date of the employee's separation, death, or transfer.

(5) An employee who has been determined by an agency to be in a continuing employment program under which the employee is required to work a ''mixed tour of duty'' will have his or her annual leave held in abeyance during intermittent duty and recredited when he or she returns to full-time or part-time employment. If the employee separates, transfers, or dies during the period of intermittent employment, he or she is entitled to a lump-sum payment for the annual leave held in abeyance. (A ''mixed tour of duty'' is a condition of employment for positions in which a fluctuating workload requires an employee to work full-time or part-time for a portion of the year and intermittent for the remainder.)

Employees not Eligible for a Lump-Sum Payment

An employee is *not* entitled to a lump-sum payment for accumulated and accrued annual leave when he or she (1) transfers between positions covered by subchapter I of chapter 63 of title 5, United States Code, except as provided by 5 U.S.C. 5551(c); (2) transfers to a position not covered by subchapter I of chapter 63 of title 5, United States Code, but to which his or her accumulated and accrued annual leave may be transferred under 5 U.S.C. 6308; (3) transfers to the government of the District of Columbia or the U.S. Postal Service; or (4) is concurrently employed in more than one part-time position and who separates from one of the part-time positions. (If an employee is employed in part-time positions in different agencies, the annual leave accumulated and accrued in the agency from which the employee separates must be transferred to the current employing agency.)

Projecting the Lump-Sum Leave Period

A lump-sum payment for accumulated and accrued annual leave equals the pay an employee would have received had he or she remained in the service until expiration of the period of annual leave. The period of leave used for calculating the lump-sum payment may not be extended due to any holiday occurring after separation. Annual leave donated under the Federal voluntary leave transfer and leave bank programs may not be included in a lump-sum payment and does not serve to extend the lump-sum leave period. (See 5 CFR 630.909(e)(2) and 630.1009(e)(1).) Compensatory time off and unused credit hours accumulated under a flexible work schedule are not annual leave. Therefore, they are not included in a lump-sum payment and do not serve to extend the lump-sum leave period. Any remaining compensatory time off or credit hours (not in excess of 24) may be paid separately as part of a final salary payment when an employee separates. (See 5 CFR 550.114(d) and 551.531(d) and 5 U.S.C. 6126.)

The lump-sum payment is projected beginning on the first workday (counting any holiday) occurring after the date of separation, death, or transfer, as applicable, and including subsequent workdays and holidays. An agency must project the lump-sum leave period so that any annual leave restored under 5 U.S.C. 6304(d) is used before projecting any accumulated annual leave to the employee's credit in his or her regular annual leave account. (Under 5 CFR 630.306 and 630.309, annual leave that is restored must be used by a certain date. Projecting the lump-sum leave period so that restored annual leave is used before regular annual leave will preclude the forfeiture of restored annual leave for employees who are reemployed in the Federal service prior to the expiration of the lump-sum leave period.)

Calculating the Lump-Sum Payment

Under 5 U.S.C. 5551, ''the lump-sum payment shall equal the pay (excluding any differential under section 5925 and any allowance under section 5928) the employee or individual would have received had he remained in the service until expiration of the period of the annual or vacation leave.'' The term ''pay'' is not further defined in law. In these proposed regulations, we have attempted to offer an interpretation of the ''pay'' to be included in a lump-sum payment that is consistent with former Federal Personnel Manual guidance, Comptroller General opinions, and agency practices.

The proposed regulations provide that the following types of pay and adjustments are to be included in a lump-sum payment for annual leave:

(1) An employee's rate of basic pay. An employee's rate of basic pay is defined as the rate fixed by law or administrative action for the position held by the employee and includes any applicable special salary rate established under 5 U.S.C. 5305 or similar provision of law or a special rate for law enforcement officers under section 403 of the Federal Employees Pay Comparability Act of 1990; a locality rate of pay under subpart F of part 531 of title 5, Code of Federal Regulations; a special law enforcement adjusted rate of pay under subpart C of part 531, including a rate continued under § 531.307; and any continued rate of pay under subpart G of part 531.

(2) Any statutory adjustments in pay and any general system-wide increases in pay that are authorized by law (or the President's alternative plan) under sections 5303, 5304, 5304a, 5305, 5318, 5363, 5372, 5372a, 5376, 5382, or 5392 of title 5, United States Code, *prior* to the date of separation, death, or transfer *and* which become effective during the lump-sum leave period. The lump-sum payment is adjusted to reflect the increased rate beginning on the effective date of the pay adjustment.

(3) For a prevailing rate employee, the scheduled rate of pay under 5 U.S.C. 5343 and any applicable wage adjustment that is determined under 5 U.S.C. 5343 if the employee separates, dies, or transfers after issuance of an official order to conduct a wage survey for his or her applicable wage area in accordance with 5 CFR 532.231(d)(3)

and which becomes effective during the lump-sum leave period. The lump-sum payment is adjusted to reflect the increased rate beginning on the effective date of the wage adjustment.

(4) A within-grade increase authorized under 5 U.S.C. 5335 (if the employee's work is of an acceptable level of competence) or under 5 U.S.C. 5343(e)(2) (if the employee's work performance rating is satisfactory or better) and the employee has completed the required waiting period prior to separation, death, or transfer. (See 5 CFR 531.404 and 532.417.)

(5) Annual premium pay for standby duty (5 U.S.C. 5545(c)(1)), annual premium pay for administratively uncontrollable overtime (AUO) work (5 U.S.C. 5545(c)(2)), and availability pay for criminal investigators (5 U.S.C. 5545a). The lump-sum payment is calculated using the percentage rate received by the employee immediately prior to separation, death, or transfer.

(6) For certain employees, night pay earned for nonovertime hours (5 U.S.C. 5545), Sunday premium pay (5 U.S.C. 5546(a)), and night differential for prevailing rate employees earned during nonovertime hours (5 U.S.C. 5343(f)).

The amount of night pay and/or Sunday premium pay to include in a lump-sum payment is based on the average amount of night pay and/or Sunday premium pay earned by the employee during the 12 administrative workweeks immediately prior to separation, death, or transfer (or a lesser period if the employee was not employed for the full 12 weeks prior to separation, death, or transfer).

Night differential for prevailing rate employees is included for all regularly scheduled nonovertime periods of night shift duty covered by the unused annual leave as if the employee had continued to work beyond the effective date of separation. The night shift differential is paid at the percentage rate received by the employee for the last full workweek immediately prior to separation. When a night shift has been formally canceled or an employee has been regularly scheduled for continuous day shift work on or before the date of separation, the lump-sum leave payment is computed on the day rate.

As a result of the decision in *Armitage, et. al.* v. *United States* (Fed. Cir. No. 92–5157, April 12, 1993), employees who are regularly scheduled to work on Sunday are entitled to Sunday premium pay for periods of paid leave. Based on this decision, OPM revised its regulations in December 1994 to require the payment of Sunday premium pay for periods of paid leave or excused absence (5 CFR 550.171). Under the proposed regulations, certain employees covered by the Armitage decision are entitled to include night pay earned during nonovertime hours, Sunday premium pay, and night differential for prevailing rate employees earned during nonovertime hours in their lump-sum payments for annual leave.

However, recently enacted legislation prohibits the use of funds appropriated by the Treasury, Postal Service, and General Government Appropriations Act, 1997, as contained in section 101(f) of Public Law 104–208, the Omnibus Consolidated Appropriations Act, 1997, for the payment of Sunday premium pay and night differential pay to employees who do not actually perform work during the time corresponding to such Sunday premium or night differential pay. This provision became effective on September 30, 1996, and will expire on September 30, 1997, unless legislation is enacted to continue it. Employees covered by this Act may not receive Sunday premium and night differential pay during periods of paid leave. The restriction on paying Sunday premium pay during periods when work is not performed has been in effect for employees of the Federal Aviation Administration under the Transportation and Related Agencies Appropriations Acts for fiscal years 1995, 1996, and 1997.

(7) Overtime pay under the Fair Labor Standards Act of 1938, as amended (FLSA), for overtime hours regularly scheduled during an employee's uncommon tour of duty as defined in 5 CFR 630.201.

(8) Nonforeign area cost-of-living allowances under 5 U.S.C. 5941, nonforeign area post differentials under 5 U.S.C. 5941, and foreign area post allowances under 5 U.S.C. 5924(1) (as authorized by section 220 of the U.S. Department of State's Standardized Regulations (Government Civilians, Foreign Areas)) if the employee was receiving such differential or allowance immediately prior to separation, death, or transfer in the nonforeign or foreign area. Current OPM regulations in 5 CFR 591.210(b)(1) already require a nonforeign area cost-of-living allowance and a nonforeign post differential to be included in a lump-sum payment if the employee separates in the nonforeign area. However, it should be noted that 5 U.S.C. 5551 specifically excludes a foreign area post differential (5 U.S.C. 5925) and foreign area danger pay (5 U.S.C. 5928) from lump-sum payments for annual leave.

OPM proposes to delegate authority to the head of each agency to determine other kinds of pay authorized in statutes other than title 5, United States Code, that should be included in a lump-sum payment, consistent with 5 U.S.C. 5551, 5552, and 6306. No other types of pay or pay adjustments may be included in a lump-sum payment for annual leave unless specifically authorized by the head of an agency through the authority delegated by OPM.

Refund of Lump-Sum Payment

Under 5 U.S.C. 6306, when an employee who receives a lump-sum payment for accumulated and accrued annual leave under 5 U.S.C. 5551 is reemployed in the Federal service prior to the end of the period covered by the lump-sum payment, the employee must refund to the employing agency an amount equal to the payment covering the period between the date of reemployment and the expiration of the lump-sum period. This rule applies whether an employee is reemployed in a position covered by chapter 63 of title 5, United States Code, or a different formal leave system. The refund is based on the pay used to compute the lump-sum payment; e.g., an employee who received a lump-sum payment based on the pay for a GS–11 position must refund the lump-sum payment based on the same GS–11 pay, even if he or she is reemployed at a lower or higher grade level. The refund is deposited in the Treasury of the United States to the credit of the employing agency.

An agency may permit an employee to refund the lump-sum payment for annual leave in installments. If an agency permits the lump-sum refund to be paid in installments, the employee must pay the lump-sum payment refund in full within 1 year after the date of reemployment. The annual leave will be recredited to the employee's annual leave account on the date the refund is paid in full.

An employee who is reemployed in the Federal service after the expiration of the lump-sum period is not required to refund any portion of a lump-sum payment. An employee who is reemployed prior to the expiration of the lump-sum period in a Federal position that does not have a formal leave system and whose annual leave cannot be recredited is not required to refund any portion of a lump-sum payment. Under 5 U.S.C. 6306(a), an employee who is reemployed in a position listed in 5 U.S.C. 6301(2)(ii), (iii), (vi), or (vii) (i.e., an intermittent position; a temporary, hourly-rate position in construction work; a position as an employee of either or both Houses of Congress; or certain positions in corporations supervised by

the Farm Credit Administration) is not required to refund any portion of a lump-sum payment.

Recredit of Annual Leave

When an individual is reemployed in the Federal service prior to the expiration of the lump-sum leave period in a position covered by subchapter I of chapter 63 of title 5, United States Code, an amount of annual leave equal to the days or hours of work remaining between the date of reemployment and the expiration of the lump-sum leave period must be recredited to the employee by the employing agency. Upon full payment of the lump-sum payment refund, the agency must recredit the employee's annual leave to his or her account. The recredited annual leave is available for use by the employee on or after the date it is recredited.

When an individual is reemployed in the Federal service prior to the expiration of the lump-sum leave period in a position covered by a different formal leave system, the amount of annual leave to be recredited to the employee by the employing agency must be converted based on the rules for recrediting annual leave in 5 CFR 630.501(b).

If any part of the lump-sum refund is for a period of annual leave restored under 5 U.S.C. 6304(d), the restored leave is credited in a separate leave account, and the expiration date for its use is the same date as that originally established during the former employment. If the originally established expiration date for the restored leave occurs before the date of reemployment, a refund is required for all of the unexpired portion, but none of that restored leave may be recredited. Therefore, an agency may wish to consider delaying the date of reemployment until expiration of the period represented by restored annual leave.

In most cases, the annual leave recredited is subject to the maximum annual leave limitation in 5 U.S.C. 6304(a), (b), (c), or (f), as appropriate, for the position in which reemployed. For example, if an employee is reemployed in a position covered by 5 U.S.C. 6304(a), the maximum annual leave limitation is 240 hours. If the annual leave to be recredited is in excess of the maximum annual leave ceiling permitted for the position in which reemployed, a new maximum leave ceiling is established for the employee as follows:

(1) If the maximum leave ceiling in the former position (prior to separation or transfer) is higher than the maximum leave ceiling in the current position in which reemployed, a new maximum annual leave ceiling is established at the lesser of: (a) The employee's former maximum annual leave ceiling at the time of separation or transfer, or (b) the amount of annual leave to be recredited. The employee's new maximum leave ceiling is subject to reduction in the same manner as provided in 5 U.S.C. 6304(c) until the employee's accumulated annual leave is equal to or less than the maximum leave ceiling for the position in which reemployed.

(2) If a member of the Senior Executive Service (SES) had a personal leave ceiling established under 5 CFR 630.301(d) prior to separation or transfer that is higher than the maximum leave ceiling in the current position in which employed, a new personal leave ceiling is established at the lesser of: (a) The employee's personal leave ceiling established under 5 CFR 630.301(d) prior to separation or transfer, or (b) the amount of annual leave to be recredited. The new personal leave ceiling is subject to reduction in the same manner as provided in 5 U.S.C. 6304(c) until the employee's accumulated annual leave is equal to or less than the maximum leave ceiling for the position in which reemployed.

Under 5 U.S.C. 6306(b), when an employee is reemployed in a position listed in 5 U.S.C. 6301(2)(x)–(xiii) (i.e., certain Presidential appointees or designees), the amount of annual leave to be recredited is to be held in abeyance and remain to the employee's credit. The employee will receive a lump-sum payment for the annual leave if he or she later separates, transfers, or dies. If, instead, the employee transfers to a position covered by chapter 63 of title 5, or to a position covered by a different formal leave system, the annual leave to the employee's credit must be recredited to the employee by the employing agency.

Income Tax and Deductions

Under 5 U.S.C. 5551, a lump-sum payment to a separated or transferred employee is considered pay for income tax purposes. A lump-sum payment is not subject to deductions for retirement under the Civil Service Retirement System or the Federal Employees Retirement System, health benefits under the Federal Employees Health Benefits program, life insurance under the Federal Employees Group Life Insurance program, or savings under the Thrift Savings Plan. An employee does not accrue leave for the period covered by the lump-sum payment. Finally, a lump-sum payment is subject to garnishment under parts 581 and 582 of title 5, Code of Federal Regulations, and to administrative offset (for collection of debts to the Federal Government under part 102 of title 4, Code of Federal Regulations).

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will affect only Federal employees and agencies.

List of Subjects in 5 CFR Part 550

Administrative practice and procedure, Claims, Government employees, Wages.

Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM is proposing to amend part 550 of title 5 of the Code of Federal Regulations as follows:

PART 550—PAY ADMINISTRATION (GENERAL)

1. Subpart L is added to read as follows:

Subpart L—Lump-sum Payment for Accumulated and Accrued Annual Leave

Subpart L—Lump-sum Payment for Accumulated and Accrued Annual Leave

Authority: 5 U.S.C. 5553, 6306, and 6311.

§ 550.1201 Purpose, applicability, and administration.

(a) *Purpose.* This subpart provides regulations to implement sections 5551, 5552, and 6306 of title 5, United States Code, and must be read together with those sections. 5 U.S.C. 5551 and 5552 provide for a lump-sum payment for accumulated and accrued annual leave when an employee enters on active duty in the armed forces and elects to receive a lump-sum payment for accumulated and accrued annual leave or separates from Federal service. 5 U.S.C. 6306 requires that when an employee is reemployed in the Federal service prior to the expiration of the lump-sum period, he or she shall refund an amount equal to the pay covering the period between the date of reemployment and the expiration of the lump-sum period.

(b) *Applicability.* This subpart applies to—

(1) Any employee who separates, dies, or transfers under the conditions prescribed in § 550.1203; and

(2) Any employee or any individual employed by a territory or possession of the United States who enters on active duty in the armed forces and who elects to receive a lump-sum payment for accumulated and accrued annual leave.

(c) *Administration.* The head of an agency having employees subject to this subpart shall be responsible for the proper administration of this subpart.

§ 550.1202 Definitions.

In this subpart—

Accumulated and accrued annual leave means any annual leave accumulated and accrued, as these terms are defined in § 630.201 of this chapter, plus any annual leave credited to an employee under 5 U.S.C. 6304(c) and § 630.301(d) of this chapter and any annual leave restored under 5 U.S.C. 6304(d). Accumulated and accrued annual leave does not include annual leave received by a leave recipient under the voluntary leave transfer and leave bank programs under subchapters III and IV of chapter 63 of title 5, United States Code, and annual leave advanced to an employee under 5 U.S.C. 6302(d).

Administrative workweek has the meaning given that term in § 610.102 of this chapter.

Agency means—

(1) An executive agency and a military department as defined in sections 105 and 102 of title 5, United States Code, respectively; and

(2) A legislative or judicial agency or a unit of the legislative or judicial branch of the Government that has positions in the competitive service.

Employee has the meaning given that term in 5 U.S.C. 2105.

Lump-sum payment means a final payment to an employee for accumulated and accrued annual leave.

Mixed tour of duty means a condition of employment for positions in which a fluctuating workload requires an employee to work full-time or part-time for a limited portion of the year and intermittent for the remainder.

Rate of basic pay means the rate of pay fixed by law or administrative action for the position held by an employee before any deductions and exclusive of additional pay of any kind.

Transfer means the movement of an employee to another position without a break in service of 1 or more workdays.

§ 550.1203 Eligibility.

(a) A lump-sum payment for accumulated and accrued annual leave shall be paid when an employee—

(1) Separates or retires from the Federal service;

(2) Dies; or

(3) Except as provided in paragraphs (c), (d), and (e), of this section, transfers to a position that is not covered by subchapter I of chapter 63 of title 5, United States Code, or to a position that is covered by a different leave system, when his or her accumulated and accrued annual leave cannot be transferred.

(b) An employee who has unused annual leave that was restored under 5 U.S.C. 6304(d)(3) shall receive a lump-sum payment for the restored annual leave from the Department of Defense (DOD) when the employee transfers to a position in any other department or agency of the Federal Government or moves to a position within DOD not located at an installation undergoing closure or realignment.

(c) An employee who enters on active duty in the armed forces may elect to receive a lump-sum payment for accumulated and accrued annual leave or may request that his or her annual leave remain to his or her credit until return from active duty. However, any annual leave previously restored under 5 U.S.C. 6304(d) may not be credited and may be paid in a lump-sum payment when the employee enters active duty.

(d) An employee who transfers to a position in a public international organization under 5 U.S.C. 3582 may elect to receive a lump-sum payment for accumulated and accrued annual leave or may request that his or her annual leave be held in abeyance for recredit upon reemployment without a break in service in the Federal service. If the employee chooses to receive a lump-sum payment and is reemployed in the Federal service within 6 months after transfer to a public international organization, he or she shall refund the amount of the lump-sum payment to the agency. An amount of leave equal to the leave represented by the refund shall be credited to the employee's account under § 550.1206.

(e) Except as provided in paragraph (d)(1) of this section, an employee who transfers to a position excepted from subchapter I of chapter 63 of title 5, United States Code, by 5 U.S.C. 6301(2) (x)–(xiii) shall not receive a lump-sum payment upon appointment to the new position. The accumulated and accrued annual leave shall be held in abeyance for recredit when the employee is subsequently reemployed without a break in service in a position to which his or her accumulated and accrued annual leave may be transferred.

(f) An employee shall receive a lump-sum payment for any annual leave restored under 5 U.S.C. 6304(d) upon transfer to a position excepted by 5 U.S.C. 6301(2) (x)–(xiii). If the employee later becomes eligible for a lump-sum payment under the conditions specified in this section, a lump-sum payment shall be paid at that time for the annual leave held in abeyance. The lump-sum payment shall be computed under § 550.1205(b) based on the pay the employee was receiving immediately before the date of the transfer to the position excepted by 5 U.S.C. 6301(2) (x)–(xiii).

(g) An employee who transfers to a position that is not covered by subchapter I of chapter 63 of title 5, United States Code, and to which only a portion of his or her accumulated and accrued annual leave may be transferred, shall have the annual leave that cannot be transferred held in abeyance for recredit when the employee is subsequently employed without a break in service in a position to which his or her accumulated and accrued annual leave may be transferred. If the employee later becomes eligible for a lump-sum payment under the conditions specified in this section, a lump-sum payment shall be paid at that time for the annual leave held in abeyance. The lump-sum payment shall be computed under § 550.1205(b) based on the pay the employee was receiving immediately before the date the transfer became effective. The employee's current employing agency shall compute and pay the lump-sum payment.

(h) An employee in a missing status (as defined in 5 U.S.C. 5561(5)) on or after January 1, 1965, shall receive a lump-sum payment for accumulated and accrued annual leave or may elect to have such annual leave restored in a separate leave account under 5 U.S.C. 6304(d)(2) upon his or her return to Federal service. The lump-sum payment shall be computed under § 550.1205(b) based on the rate of pay in effect at the time the annual leave became subject to forfeiture under 5 U.S.C. 6304(a), (b), or (c).

(i) A lump-sum payment for accumulated or accrued annual leave shall not be paid to—

(1) An employee who transfers between positions covered by subchapter I of chapter 63 of title 5, United States Code, except to the extent provided by paragraph (b) of this section;

(2) An employee who transfers to a position not covered by subchapter I of chapter 63 of title 5, United States Code, but to which his or her accumulated and

accrued annual leave may be transferred;

(3) An employee who transfers to the government of the District of Columbia or the U.S. Postal Service;

(4) An employee who is concurrently employed in more than one part-time position and who separates from one of the part-time positions, in which case (if the part-time positions are in different agencies) the annual leave accumulated and accrued in the agency from which the employee separates shall be transferred to the current employing agency;

(5) A nonappropriated fund employee of the Department of Defense or the Coast Guard who moves without a break in service of more than 3 days to an appropriated fund position within the Department of Defense or the Coast Guard, respectively, under 5 U.S.C. 6308(b); or

(6) An employee who is determined by an agency to be in a continuing employment program under which the employee is required to work a mixed tour of duty. (The annual leave shall be held in abeyance during intermittent duty and recredited when the employee returns without a break in service to full-time or part-time employment. In addition, any fractional hours of creditable service for annual leave accrual purposes under § 630.204 of this chapter shall be held in abeyance and recredited when the employee returns to full-time or part-time employment.)

§ 550.1204 Projecting the lump-sum leave period.

(a) A lump-sum payment shall equal the pay an employee would have received if he or she had remained in the Federal service until the expiration of the accumulated and accrued annual leave to the employee's credit. The lump-sum period shall be projected beginning on the first workday (counting any holiday) occurring after the date of separation, death, or transfer under the conditions prescribed in § 550.1203 and shall continue counting all subsequent workdays and holidays until the expiration of the period of annual leave. The period of leave used for calculating the lump-sum payment shall not be extended by any holidays under 5 U.S.C. 6103 or applicable Executive order occurring after the date of separation, death, or transfer; annual leave donated to an employee under the leave transfer or leave bank programs under subparts I and J of part 630 of this chapter; compensatory time off earned under 5 U.S.C. 5543 and §§ 550.114(d) or 551.531; or credit hours accumulated under an alternative work schedule under 5 U.S.C. 6126.

(b) For employees whose annual leave was held in abeyance immediately prior to becoming eligible for a lump-sum payment, the lump-sum payment shall be projected beginning on the first workday occurring after the date of separation, death, or transfer under the conditions prescribed in § 550.1203.

(c) An agency shall project the lump-sum leave period so that any annual leave restored under 5 U.S.C. 6304(d) in a separate leave account expires before projecting any accumulated annual leave to the employee's credit in his or her regular annual leave account.

§ 550.1205 Calculating a lump-sum payment.

(a) A lump-sum payment shall be computed based on the types of pay in paragraph (b) of this section in effect at the time an employee becomes eligible for a lump-sum payment under the conditions prescribed in § 550.1203 and any adjustments in pay included in paragraphs (b) (2), (3), and (4) of this section. An agency shall calculate a lump-sum payment by multiplying the number of hours of accumulated and accrued annual leave by the applicable hourly rate of pay, including types of pay listed in paragraph (b) of this section, or by using a mathematically equivalent method, such as multiplying weeks of annual leave by the applicable weekly rate of pay. If a lump-sum payment is calculated using weekly rates, the number of weeks of annual leave must be rounded to the fourth decimal place (e.g., 0.4444). An annual rate of pay shall be converted to an hourly rate of pay by dividing the annual rate of pay by 2,087 and rounding to the nearest cent, counting one-half cent and over as the next higher cent.

(b) A lump-sum payment shall be computed using the following types of pay and pay adjustments, as applicable:

(1) The greatest of the following rates of pay:

(i) An employee's rate of basic pay, including any applicable special salary rate established under 5 U.S.C. 5305 or similar provision of law or a special rate for law enforcement officers under section 403 of the Federal Employees Pay Comparability Act of 1990 (FEPCA), Public Law 101–509, 104 Stat. 1465;

(ii) A locality rate of pay under subpart F of part 531 of this chapter or similar provision or law, where applicable;

(iii) A special law enforcement adjusted rate of pay under subpart C of part 531 of this chapter, where applicable, including a rate continued under § 531.307 of this chapter; or

(iv) A continued rate of pay under subpart G of part 531 of this chapter.

(2) Any statutory adjustments in pay or any general system-wide increases in pay that are authorized by law or the President's alternative plan, such as adjustments under sections 5303, 5304, 5305, 5318, 5363, 5372, 5372a, 5376, 5382, or 5392 of title 5, United States Code, prior to the date of separation, death, or transfer, and which become effective during the lump-sum leave period. The lump-sum payment shall be adjusted to reflect the increased rate on and after the effective date of the pay adjustment.

(3) In the case of a prevailing rate employee, a lump-sum payment shall include the scheduled rate of pay under 5 U.S.C. 5343 and any applicable adjustments in prevailing rates that are determined under 5 U.S.C. 5343 when the employee separates after issuance of an official order to conduct a wage survey for his or her applicable wage area in accordance with 5 CFR 532.231(d)(3) and which become effective during the lump-sum leave period. The lump-sum payment shall be adjusted to reflect the increased prevailing rate on and after the effective date of the rate adjustment.

(4) A within-grade increase under 5 U.S.C. 5335 or 5 U.S.C. 5343(e)(2) if the employee has met the requirements of § 531.404 or § 532.417 of this chapter prior to separation, death, or transfer, as applicable.

(5) The following types of premium pay:

(i) Night differential under 5 U.S.C. 5343(f) for nonovertime hours at the percentage rate received by a prevailing rate employee for the last full workweek immediately prior to separation, death, or transfer;

(ii) Night pay under 5 U.S.C. 5545 for nonovertime hours based on the average amount of night pay received by an employee during the 12 workweeks immediately prior to the date the employee became eligible for a lump-sum payment (or a lesser period if the employee was not employed in the position for at least 12 workweeks immediately prior to the date he or she became eligible for a lump-sum payment);

(iii) Sunday premium pay under 5 U.S.C. 5546(a) for nonovertime hours on Sunday based on the average amount of Sunday premium pay received by the employee during the 12 workweeks immediately prior to the date the employee became eligible for a lump-sum payment (or a lesser period if the employee was not employed in the position for at least 12 workweeks immediately prior to the date the

employee became eligible for a lump-sum payment); and

(iv) Premium pay under 5 U.S.C. 5545(c) or 5545a if the employee was receiving premium pay immediately prior to separation, death, or transfer under the conditions prescribed in § 550.1203. The lump-sum payment shall be based on the percentage rate received by the employee immediately prior to separation, death, or transfer.

(6) Overtime pay under the Fair Labor Standards Act of 1938, as amended (FLSA), for overtime work that is regularly scheduled during an employee's established uncommon tour of duty as defined in § 630.201 of this chapter if such uncommon tour of duty was applicable to the employee immediately prior to separation, death, or transfer under the conditions prescribed in § 550.1203. The lump-sum payment shall include the amount of FLSA overtime pay for regularly scheduled overtime work ordered or approved at the time of separation, death, or transfer.

(7) A cost-of-living allowance and/or post differential in a nonforeign area under 5 U.S.C. 5941 if the employee was receiving the allowance and/or post differential immediately prior to separation, death, or transfer in the nonforeign area.

(8) A post allowance in a foreign area under 5 U.S.C. 5924(1) and the *Standardized Regulations* (Government Civilians, Foreign Areas) if the employee was receiving the post allowance immediately prior to separation, death, or transfer in the foreign area.

(c) The head of an agency shall prescribe regulations or standards for the inclusion of any other kinds of pay authorized in statutes other than title 5, United States Code, in a lump-sum payment. Such regulations or standards shall be consistent with 5 U.S.C. 5551, 5552, 6306, and other applicable provisions of law.

(d) Except as provided in paragraph (c) of this section, a lump-sum payment shall exclude any other pay not specifically listed in paragraph (b) of this section.

(e) An employee shall not earn leave for the period covered by a lump-sum payment.

(f) A lump-sum payment is not subject to deductions for retirement under the Civil Service Retirement System or the Federal Employees Retirement System established by chapters 83 and 84 of title 5, United States Code, respectively; health benefits under the Federal Employees Health Benefits program established by chapter 89 of title 5, United States Code; life insurance under the Federal Employees Group Life Insurance program established by chapter 87 of title 5, United States Code; and savings under the Thrift Savings Plan established by subchapter III of chapter 84 of title 5, United States Code.

(g) When a reemployed annuitant's pay is reduced in accordance with 5 CFR 831.702 of this chapter, the reemployed annuitant's lump-sum payment at the time of his or her separation, death, or transfer under the conditions prescribed in § 550.1203 shall be computed using his or her pay before such reduction.

(h) A lump-sum payment is subject to garnishment under parts 581 and 582 of this chapter and to administrative offset (for recovery of debts to the Federal Government) under 4 CFR part 102.

§ 550.1206 Refund of lump-sum payment and recredit of annual leave.

(a) Except as provided in paragraphs (d), (e), and (f) of this section, when an employee who receives a lump-sum payment for accumulated and accrued annual leave under 5 U.S.C. 5551 is reemployed in the Federal service prior to the end of the period covered by the lump-sum payment, the employee shall refund to the employing agency an amount equal to the pay included in the lump-sum payment under § 550.1205(b) that covers the period between the date of reemployment and the expiration of the lump-sum period. The refund shall be computed based on the pay used to compute the lump-sum payment under § 550.1205(b). An agency may permit an employee to refund the lump-sum payment for annual leave in installments. If an agency permits the lump-sum refund to be paid in installments, the employee shall pay the lump-sum payment refund in full within 1 year after the date of reemployment.

(b) An amount of annual leave equal to the days or hours of work remaining between the date of reemployment and the expiration of the lump-sum period shall be recredited to the employee when the full refund is paid to the agency. The recredited annual leave shall be made available for use by the employee on and after the date the annual leave is recredited. Annual leave shall be recredited as follows:

(1) When an employee is reemployed in the Federal service in a position covered by subchapter I of chapter 63 of title 5, United States Code, an amount of annual leave equal to the days or hours of work remaining between the date of reemployment and the expiration of the lump-sum period shall be recredited to the employee by the employing agency.

(2) When an employee is reemployed in the Federal service in a position that is not covered by subchapter I of chapter 63 of title 5, United States Code, but is covered by a different leave system, an amount of annual leave representing the days or hours of work remaining between the date of reemployment and the expiration of the lump-sum period, as determined under § 630.501(b) of this chapter, shall be recredited to the employee by the employing agency. If the unexpired period of leave covers a larger amount of leave than can be recredited under a different leave system, the employee shall refund only the amount that represents the leave that can be recredited.

(3) If any part of the lump-sum refund made under paragraph (a) of this section reflects annual leave restored under 5 U.S.C. 6304(d), the annual leave shall be restored in a separate account, and the time limit for using the restored annual leave shall be the same as that originally established under § 630.306 of this chapter prior to the employee's separation or transfer under the conditions prescribed in § 550.1203.

(c) Except as provided in paragraph (d) of this section, the annual leave recredited under paragraph (b) of this section shall be subject to the maximum annual leave limitation established under 5 U.S.C. 6304 (a), (b), (c), or (f), as appropriate, for the position in which reemployed.

(d) If the annual leave recredited to an employee under paragraph (b) of this section is in excess of the maximum annual leave limitation established under 5 U.S.C. 6304 (a), (b), (c), or (f), as appropriate, for the position in which reemployed, the employee's maximum annual leave limitation shall be determined as follows:

(1) If at the time of separation or transfer an employee was subject to a higher maximum annual leave limitation than the maximum annual leave limitation for the position in which reemployed, a new maximum annual leave limitation shall be established at the lesser of the employee's former maximum annual leave limitation at the time of separation or transfer or the amount of annual leave to be recredited to the employee under paragraph (b) of this section. The new maximum annual leave limitation shall be subject to reduction in the same manner as provided in 5 U.S.C. 6304(c) until the employee's accumulated annual leave is equal to or less than the maximum annual leave limitation for the position in which reemployed.

(2) A member of the Senior Executive Service (SES) who had a personal leave ceiling established under § 630.301(d) of

this chapter and who is reemployed in a position covered by subchapter I of chapter 63 of title 5, United States Code, shall have a new personal leave ceiling established at the lesser of his or her personal leave ceiling established under § 630.301(d) of this chapter at the time of separation or transfer or the amount of annual leave to be recredited to the SES member under paragraph (b) of this section. The new personal leave ceiling shall be subject to reduction in the same manner as provided in 5 U.S.C. 6304(c) until the SES member's accumulated annual leave is equal to or less than the maximum annual leave limitation for the position in which reemployed.

(e) An employee who is reemployed in a position listed in 5 U.S.C. 6301(2)(ii), (iii), (vi), or (vii) shall not be required to refund a lump-sum payment under paragraph (a) of this section.

(f) An employee who is reemployed in a position that has no leave system to which annual leave can be recredited shall not be required to refund a lump-sum payment under paragraph (a) of this section.

(g) When an employee is reemployed in a position listed in 5 U.S.C. 6301(2)(x)–(xiii), the amount of annual leave to be recredited to the employee under paragraph (b) of this section shall remain to the employee's credit and shall become payable when the employee becomes eligible for a lump-sum payment under the conditions prescribed in § 550.1203. If the employee subsequently transfers to a position covered by subchapter I of chapter 63 of title 5, United States Code, or to a position under a different formal leave system to which his or her annual leave can be recredited, the annual leave to the employee's credit shall be recredited to the employee by the employing agency under § 550.1206(b)(1).

(h) An agency shall document the calculation of an employee's lump-sum payment as provided in § 550.1205(b) so as to permit the subsequent calculation of any refund required under paragraph (a) of this section and any recredit of annual leave required under paragraph (b) of this section.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 905

[Docket No. FV97–905–1 PR]

Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Limiting the Volume of Small Florida Red Seedless Grapefruit

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites comments on limiting the volume of small red seedless grapefruit entering the fresh market under the marketing order covering oranges, grapefruit, tangerines, and tangelos grown in Florida. The marketing order is administered locally by the Citrus Administrative Committee (committee). This rule would limit the volume of size 48 and/or size 56 red seedless grapefruit handlers could ship during the first 11 weeks of the 1997–1998 season that begins in September. This proposal would provide a sufficient supply of small sized red seedless grapefruit to meet market demand, without saturating all markets with these small sizes. The committee believes this rule is necessary to help stabilize the market and improve grower returns.

DATES: Comments must be received by August 13, 1997.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, room 2525-S, P.O. Box 96456, Washington, DC 20090–6456; Fax: (202) 720–5698. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: William G. Pimental, Southeast Marketing Field Office, AMS, USDA, P.O. Box 2276, Winter Haven, Florida 33883–2276; telephone: (941) 299–4770, Fax: (941) 299–5169; or Anne Dec, Marketing Order Administration Branch, F&V, AMS, USDA, room 2522–S, P.O. Box 96456, Washington, DC 20090–6456; telephone: (202) 720–5053, Fax: (202) 720–5698. Small businesses may request information on compliance with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, room 2525–S, P.O. Box 96456, Washington, DC 20090–6456; telephone (202) 720–2491, Fax: (202) 720–5698.

SUPPLEMENTARY INFORMATION: This proposal is issued under Marketing Agreement No. 84 and Marketing Order No. 905, both as amended (7 CFR part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, hereinafter referred to as the ''order.'' The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This proposal will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after date of the entry of the ruling.

The order provides for the establishment of grade and size requirements for Florida citrus, with the concurrence of the Secretary. These grade and size requirements are designed to provide fresh markets with citrus fruit of acceptable quality and size. This helps create buyer confidence and contributes to stable marketing conditions. This is in the interest of growers, handlers, and consumers, and is designed to increase returns to Florida citrus growers. The current minimum grade standard for red seedless grapefruit is U.S. No. 1, and the minimum size requirement is size 56 (at least 3$\frac{5}{16}$ inches in diameter).

Section 905.52 of the order provides authority to limit shipments of any grade or size, or both, of any variety of Florida citrus. Such limitations may restrict the shipment of a portion of a specified grade or size of a variety. Under such a limitation, the quantity of such grade or size that may be shipped by a handler during a particular week would be established as a percentage of the total shipments of such variety by such handler in a prior period, established by the committee and approved by the Secretary, in which the handler shipped such variety.

Section 905.153 of the order provides procedures for limiting the volume of small red seedless grapefruit entering the fresh market. The procedures specify that the committee may recommend that only a certain percentage of sizes 48 and/or 56 red seedless grapefruit be made available for shipment into fresh market channels for any week or weeks during the regulatory period. The 11 week period begins the third Monday in September. Under such a limitation, the quantity of sizes 48 and/or 56 red seedless grapefruit that may be shipped by a handler during a regulated week is calculated using the recommended percentage. By taking the recommended weekly percentage times the average weekly volume of red grapefruit handled by such handler in the previous five seasons, handlers can calculate the volume of sizes 48 and/or 56 they may ship in a regulated week.

This proposed rule would limit the volume of small red seedless grapefruit entering the fresh market for each week of the 11 week period beginning the week of September 15. The proposal would limit the volume of sizes 48 and/or 56 red seedless grapefruit by establishing the weekly percentage for each of the 11 weeks at 25 percent. This action was recommended by the committee at its meeting on May 28, 1997, by a vote of 10 in favor to 7 opposed.

For the past few seasons, returns on red seedless grapefruit have been at all time lows, often not returning the cost of production. On tree prices for red seedless grapefruit have declined steadily from $9.60 per carton (3/5 bushel) during the 1989–90 season, to $3.45 per carton during the 1994–95 season, to a low of $1.41 per carton during the 1996–97 season. The committee believes that to stabilize the market and improve returns to growers, demand for fresh red seedless grapefruit must be stabilized and increased.

One problem contributing to the current state of the market is the excessive number of small sized grapefruit shipped early in the marketing season. During the past three seasons, sizes 48 and 56 accounted for 34 percent of total shipments during the 11 week regulatory period, with the average weekly percentage exceeding 40 percent of shipments. This contrasts with sizes 48 and 56 representing only 26 percent of total shipments for the remainder of the season. While there is a market for early grapefruit, the shipment of large quantities of small red seedless grapefruit in a short period oversupplies the fresh market for these sizes and negatively impacts the market for all sizes.

For the majority of the season, larger sizes return better prices than smaller sizes. However, there is a push early in the season to get fruit into the market to take advantage of the higher prices available at the beginning of the season. The early season crop tends to have a greater percentage of small sizes. This creates a glut of smaller, lower priced fruit on the market that drives down the price for all sizes. Early in the season, larger sized fruit commands a premium price. In some cases, the f.o.b. is $4 to $6 a carton more than for the smaller sizes. In early October, the f.o.b. for a size 27 averages around $10.00 per carton. This compares to an average f.o.b. of $5.50 per carton for size 56. By the end of the 11 week period outlined in this rule, the f.o.b. for large sizes has dropped to within two dollars of the f.o.b. for small sizes.

In the past three seasons, during the period covered by this rule, prices of red seedless grapefruit have fallen from a weighted average f.o.b. of $7.80 per carton to an average f.o.b. of $5.50 per carton. Even though later in the season the crop has sized to naturally limit the amount of smaller sizes available for shipment, the price structure in the market has already been negatively affected. In the past three years, the market has not recovered, and the f.o.b. for all sizes fell to around $5.00 to $6.00 per carton for most of the rest of the season.

The committee discussed this issue at length at several meetings. The committee believes that the overshipment of smaller sized red seedless grapefruit early in the season has contributed to below production cost returns for growers and lower on tree values. An economic study done by the University of Florida—Institute of Food and Agricultural Sciences (UF-IFAS) in May 1997, found that on tree prices have fallen from a high near $7.00 in 1991–92 to around $1.50 for this past season. The study projects that if the industry elects to make no changes, the on tree price will remain around $1.50. The study also indicates that increasing minimum size restrictions could help to raise returns.

The committee examined shipment data covering the 11 week regulatory period for the last four seasons. The information contained the amounts and percentages of sizes 48 and 56 shipped during each week. They compared this information with tables outlining weekly f.o.b. figures for each size. Based on this statistical information from past seasons, the committee members believe there is an indication that once shipments of sizes 48 and 56 reach levels above 250,000 cartons a week, prices decline on those and most other sizes of red seedless grapefruit. Without volume regulation, the industry has been unable to limit the shipments of small sizes. The committee believes that if shipments of small sizes could be maintained at around 250,000 cartons a week, prices should stabilize and demand for larger, more profitable sizes should increase.

The committee discussed at what level to establish the weekly percentages. They wanted to recommend a weekly percentage that would provide a sufficient volume of small sizes without adversely impacting the markets for larger sizes. The committee recommended that the percentage for each of the 11 weeks be established at the 25 percent level. This percentage, when combined with the average weekly shipments for the total industry, would provide a total industry allotment of 244,195 cartons of sizes 48 and/or 56 red seedless grapefruit per regulated week. This percentage would allow the total shipments of small red seedless grapefruit to approach the 250,000 carton mark during regulated weeks without exceeding it.

In its deliberations, the committee also recognized that if crop and market conditions should change, the committee could recommend that the percentage be increased or eliminated to provide for the shipment of more small sizes in any one, or all of the 11 weeks. While the official crop estimate will not be available until October, information in the UF-IFAS study and committee discussions indicate that the 1997–98 season production will be near or greater than the 1996–97 estimate of 30.8 million boxes (1⅗ bushel) of red seedless grapefruit. Committee members also stated that the crop is sizing well and should produce a greater number of larger sizes than the past season. Using this information on the 1997–98 crop, the committee members thought that establishing a weekly percentage of 25 percent would provide enough small sizes to supply those markets without disrupting the markets for larger sizes.

Under the procedures in section 905.153, the quantity of sizes 48 and/or 56 red seedless grapefruit that may be shipped by a handler during a regulated week would be calculated using the recommended percentage of 25 percent. By taking the 25 percent weekly percentage times the average weekly volume of red grapefruit handled by such handler in the previous five seasons, handlers can calculate the volume of sizes 48 and/or 56 they may ship in a regulated week.

An average week has been calculated by the committee for each handler using the following formula. The total red seedless grapefruit shipments by a handler during the 33 week period beginning the third Monday in September and ending the first Sunday in May during the previous five seasons are added and divided by five to establish an average season. This average season was then divided by the 33 weeks in a season to derive the average week. This average week would be the base for each handler for each of the 11 weeks contained in the regulation period. The weekly percentage, in this case, 25 percent, is multiplied by a handler's average week. The total is that handler's allotment of sizes 48 and/or 56 red seedless grapefruit for the given week.

Under this proposed rule, the calculated allotment is the amount of small sized red seedless grapefruit a handler could ship. If the minimum size established under section 905.52 remains at size 56, handlers could fill their allotment with size 56, size 48, or a combination of the two sizes such that the total of these shipments are within the established limits. If the minimum size under the order is 48, handlers could fill their allotment with size 48 fruit such that the total of these shipments are within the established limits. The committee staff would perform the specified calculations and provide them to each handler.

To illustrate, suppose Handler A shipped a total of 50,000 cartons, 64,600 cartons, 45,000 cartons, 79,500 cartons, and 24,900 cartons of red seedless grapefruit in the last five seasons, respectively. Adding these season totals and dividing by five yields an average season of 52,800 cartons. The average season would then be divided by 33 weeks to yield an average week, in this case, 1,600 cartons. This would be Handler A's base. The weekly percentage of 25 percent would then be applied to this amount. This would provide this handler with a weekly allotment of 400 cartons ($1,600 \times .25$) of size 48 and/or 56.

The average week for handlers with less than five previous seasons of shipments would be calculated by the committee by averaging the total shipments for the seasons they did ship red seedless grapefruit during the immediately preceding five years and dividing that average by 33. New handlers with no record of shipments would have no prior period on which to base their average week. Therefore, under this proposal, a new handler could ship small sizes equal to 25 percent of their total volume of shipments during their first shipping week. Once a new handler has established shipments, their average week will be calculated as an average of the weeks they have shipped during the current season.

This proposed rule would establish a weekly percentage of 25 percent for each of the 11 weeks to be regulated. The regulatory period runs from the third Monday in September (September 15, 1997) through the last Sunday in November (November 30, 1997). Each regulation week would begin Monday at 12:00 a.m. and end at 11:59 p.m. the following Sunday, since most handlers keep records based on Monday being the beginning of the work week. If necessary, the committee could meet and recommend a percentage above 25 percent to the Secretary at any time during the regulatory period.

The rules and regulations contain a variety of provisions designed to provide handlers with some marketing flexibility. When regulation is established by the Secretary for a given week, the committee calculates the quantity of small red seedless grapefruit which may be handled by each handler. Section 905.153(d) provides allowances for overshipments, loans, and transfers of allotment. These allowances should allow handlers the opportunity to supply their markets while limiting the impact of small sizes on a weekly basis.

During any week for which the Secretary has fixed the percentage of sizes 48 and/or 56 red seedless grapefruit, any handler could handle an amount of sizes 48 and/or 56 red seedless grapefruit not to exceed 110 percent of their allotment for that week. The quantity of overshipments (the amount shipped in excess of a handler's weekly allotment) would be deducted from the handler's allotment for the following week. Overshipments would not be allowed during week 11 because there would be no allotments the following week from which to deduct the overshipments.

If handlers fail to use their entire allotments in a given week, the amounts undershipped would not be carried forward to the following week. However, a handler to whom an allotment has been issued could lend or transfer all or part of such allotment (excluding the overshipment allowance) to another handler. In the event of a loan, each party would, prior to the completion of the loan agreement, notify the committee of the proposed loan and date of repayment. If a transfer of allotment is desired, each party would promptly notify the committee so that proper adjustments of the records could be made. In each case, the committee would confirm in writing all such transactions prior to the following week. The committee could also act on behalf of handlers wanting to arrange allotment loans or participate in the transfer of allotment. Repayment of an allotment loan would be at the discretion of the handlers party to the loan.

The committee would compute each handler's allotment by multiplying the handler's average week by the percentage established by regulation for that week. The committee would notify each handler prior to that particular week of the quantity of sizes 48 and 56 red seedless grapefruit such handler could handle during a particular week, making the necessary adjustments for overshipments and loan repayments.

This rule does not affect the provision that handlers may ship up to 15 standard packed cartons (12 bushels) of fruit per day exempt from regulatory requirements. Fruit shipped in gift packages that are individually addressed and not for resale, and fruit shipped for animal feed are also exempt from handling requirements under specific conditions. Also, fruit shipped to commercial processors for conversion into canned or frozen products or into a beverage base are not subject to the handling requirements under the order.

During committee deliberations, several concerns were raised regarding this proposed regulation. One area of concern was the possible impact this regulation may have on exports. Several members stated that there is a strong demand in some export markets for small sizes. Other members responded that the percentage set should allow handlers enough volume of small sizes to meet the demand in these markets. It was also stated that any shortfall an individual handler might have could be filled by loan or transfer. There was also some discussion that markets that normally demand small sizes have shown a willingness to purchase larger sizes. In addition, committee data indicate that the majority of export shipments occur after the 11 week

period when there are no restrictions on small sizes.

Another concern raised was the effect this proposal may have on packouts. It was stated that this rule could reduce the volume packed, resulting in higher packinghouse costs. The purpose of this rule is to limit the volume of small sizes marketed early in the season. Larger sizes could be substituted for smaller sizes with a minimum effect on overall shipments. This rule may require more selective picking of only the sizes desired, something that many growers are doing already. The UF–IFAS study presented indicated that it would increase returns if growers would harvest selectively and return to repick groves as the grapefruit sized. This also would allow growers to maximize returns on fresh grapefruit by not picking unprofitable grades and sizes of red grapefruit that would be sent to the less profitable processing market. The study also indicated that selective harvesting can reduce the f.o.b. cost per carton. Therefore, this action should have a positive impact on grower returns.

Several members were concerned about what would happen if market conditions were to change. Other committee members responded that if industry conditions were to change (for example, if there was a freeze, or if the grapefruit was not sizing), the committee would meet and recommend that the percentage be raised to allow for more small sizes, or that the limits be removed all together.

Another concern raised was that market share could be lost to Texas. According to the Economic Analysis Branch (EAB), of the Fruit and Vegetable Division, of the Agricultural Marketing Service (AMS), limiting shipments of small Florida grapefruit would probably not result in a major shift to Texas grapefruit because the Texas industry is much smaller and would have higher freight costs to some markets supplied by Florida. The UF–IFAS study made similar findings. Texas production is much smaller and has been susceptible to freezes that take it out of the market. This has lessened its impact on the overall grapefruit market.

One handler expressed that they ship early in the season and this action could be very restrictive. Members responded that the availability of loans and transfers would address these concerns. There was also discussion of how restrictive this proposal would actually be. Based on shipments from the past four seasons, available allotment would have exceeded actual shipments for each of the first three weeks that would be regulated under this rule. In the three seasons prior to last season, if a 25 percent restriction on small sizes had been applied during the 11 week period, only an average of 4.2 percent of overall shipments during that period would have been affected. A large percentage of this volume most likely could have been replaced by larger sizes. A sufficient volume of small sized red grapefruit would still be allowed into all channels of trade, and allowances would be in place to help handlers address any market shortfall.

After considering the concerns expressed, and the available information, the committee determined that this rule was needed to regulate shipments of small sized red seedless grapefruit.

Section 8(e) of the Act requires that whenever grade, size, quality or maturity requirements are in effect for certain commodities under a domestic marketing order, including grapefruit, imports of that commodity must meet the same or comparable requirements. This rule does not change the minimum grade and size requirements under the order, only the percentages of sizes 48 and/or 56 red grapefruit that may be handled. Therefore, no change is necessary in the grapefruit import regulations as a result of this action.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 80 handlers subject to regulation under the order and approximately 11,000 growers of citrus in the regulated area. Small agricultural service firms, which includes handlers, have been defined by the Small Business Administration (SBA) (13 CFR 121.601) as those having annual receipts of less than $5,000,000, and small agricultural producers are defined as those having annual receipts of less than $500,000.

Based on the Florida Agricultural Statistics Service and committee data for the 1995–96 season, the average annual f.o.b. price for fresh Florida red grapefruit during the 1995–96 season was $5.00 per 4/5 bushel cartons for all grapefruit shipments, and the total shipments for the 1995–96 season were 23 million cartons of grapefruit. Approximately 20 percent of all handlers handled 60 percent of Florida grapefruit shipments. In addition, many of these handlers ship other citrus fruit and products which are not included in committee data but would contribute further to handler receipts. Using the average f.o.b. price, about 80 percent of grapefruit handlers could be considered small businesses under SBA's definition and about 20 percent of the handlers could be considered large businesses. The majority of Florida grapefruit handlers, and growers may be classified as small entities.

The committee believes that the overshipment of smaller sized red seedless grapefruit early in the season has contributed to below production cost returns for growers and lower on tree values. For the past few seasons, returns on red seedless grapefruit have been at all time lows, often not returning the cost of production. On tree prices for red seedless grapefruit have declined steadily from $9.60 per carton (3/5 bushel) during the 1989–90 season, to $3.45 per carton during the 1994–95 season, to a low of $1.41 per carton during the 1996–97 season. The committee believes that to stabilize the market and improve returns to growers, demand for fresh red seedless grapefruit must be stabilized and increased.

Under the authority of section 905.52 of the order, this proposed rule would limit the volume of small red seedless grapefruit entering the fresh market for each week of the 11 week period beginning the week of September 15. The proposal would limit the volume of sizes 48 and/or 56 red seedless grapefruit by establishing the weekly percentage for each of the 11 weeks at 25 percent. Under such a limitation, the quantity of sizes 48 and/or 56 red seedless grapefruit that may be shipped by a handler during a particular week is calculated using the recommended percentage. By taking the recommended percentage times the average weekly volume of red grapefruit handled by such handler in the previous five seasons, the committee would calculate a handler's weekly allotment of small sizes. This proposal would provide a supply of small sized red seedless grapefruit sufficient to meet market demand, without saturating all markets with these small sizes. The committee believes this rule is necessary to help stabilize the market and improve grower returns.

At the meeting, there was discussion regarding the expected impact of this

change on handlers and growers in terms of cost. Discussion focused on the possibility that market share would be lost to Texas and that this proposed rule could increase packinghouse costs. According to EAB, limiting shipments of small Florida grapefruit would probably not result in a major shift to Texas grapefruit because the Texas industry is much smaller and would have higher freight costs to some markets supplied by Florida. The UF–IFAS study made similar findings. Texas production is much smaller and has been susceptible to freezes that take it out of the market. This has lessened its impact on the overall grapefruit market.

The concern about packinghouse costs was that this proposal would mean lower packouts which may increase cost. However, the availability of loans and transfers would provide some flexibility. Also, this proposal would only affect small sizes and only during the 11 week period. By substituting larger sizes and using loans and transfers, packouts should approach the weekly volume of seasons prior to this proposal.

The weekly percentage of 25 percent, when combined with the average weekly shipments for the total industry, would provide a total industry allotment of 244,195 cartons of sizes 48 and/or 56 red seedless grapefruit per regulated week. Based on shipments from the past four seasons, the total available weekly allotment of 244,195 cartons would exceed actual shipments for each of the first three weeks that would be regulated under this rule. In addition, if a 25 percent restriction on small sizes had been applied during the 11 week period in the three seasons prior to last season, an average of 4.2 percent of overall shipments during that period would have been affected. A large percentage of this volume most likely could have been replaced by larger sizes. Under this proposal a sufficient volume of small sized red grapefruit would still be allowed into all channels of trade, and allowances would be in place to help handlers address any market shortfall. Therefore, the overall impact on total seasonal shipments and on industry cost should be minimal.

The committee also discussed the state of the market and the cost of doing nothing. During the past three seasons, sizes 48 and 56 accounted for 34 percent of total shipments during the 11 week regulatory period, with the average weekly percentage exceeding 40 percent of shipments. For the remainder of the season, sizes 48 and 56 represent only 26 percent of total shipments. While there is a market for early grapefruit, the shipment of large quantities of small red seedless grapefruit in a short period oversupplies the fresh market for these sizes and negatively impacts the market for all sizes.

The early season crop tends to have a greater percentage of small sizes. The large volume of smaller, lower priced fruit drives down the price for all sizes. Early in the season, larger sized fruit commands a premium price. In some cases, the f.o.b. is $4 to $6 a carton more than for the smaller sizes. In early October, the f.o.b. for a size 27 averages around $10.00 per carton. This compares to an average f.o.b. of $5.50 per carton for size 56. By the end of the 11 week period outlined in this rule, the f.o.b. for large sizes has dropped to within two dollars of the price for small sizes.

In the past three seasons, during the period covered by this rule, prices of red seedless grapefruit have fallen from a weighted average f.o.b. of $7.80 per carton to an average f.o.b. of $5.50 per carton. Even though later in the season the crop has sized to naturally limit the amount of smaller sizes available for shipment, the price structure in the market has already been negatively affected. This leaves the f.o.b. for all sizes around $5.00 to $6.00 per carton for the rest of the season.

As previously stated, the on tree price of red seedless grapefruit has also been falling. On tree prices for fresh red seedless grapefruit have declined steadily from $9.60 per carton during the 1989–90 season, to $3.45 per carton during the 1994–95 season, to a low of $1.41 per carton during the 1996–97 season. In many cases, prices during the past two seasons have provided returns less than production costs. This price reduction could force many small growers out of business. If no action is taken, the UF–IFAS study indicates that on tree returns would remain at levels around $1.50.

This proposal would provide a supply of small sized red seedless grapefruit to meet market demand, without saturating all markets with these small sizes. The committee believes that if the supply of small sizes were limited early in the season, prices could be stabilized at a higher level. This would provide increased returns for growers. In addition, if more small grapefruit were allowed to remain on the tree to increase in size and maturity, it could provide greater returns to growers.

The committee surveyed shipment data covering the 11 week regulatory period for the last four seasons and examined tables outlining weekly f.o.b. figures for each size. The committee believes that if shipments of small sizes could be maintained at around 250,000 cartons a week, prices should stabilize and demand for larger, more profitable sizes should increase. The weekly percentage of 25 percent, when combined with the average weekly shipments for the total industry, would provide a total industry allotment of 244,195 cartons of sizes 48 and/or 56 red seedless grapefruit per regulated week. A stabilized price that returns a fair market value would be beneficial to both small and large growers and handlers.

This rule may require more selective picking of only the sizes desired, something that many growers are doing already. The UF–IFAS study indicated that returns could increase if growers would harvest selectively and return to repick groves as the grapefruit sized. This also would allow growers to maximize returns on fresh grapefruit by not picking unprofitable grades and sizes of red grapefruit that would be sent to the less profitable processing market. The study indicated that selective harvesting can reduce the f.o.b. cost per carton. The study also indicates that increasing minimum size restrictions could help to raise returns.

Fifty-nine percent of red seedless grapefruit is shipped to fresh market channels. There is a processing outlet for grapefruit not sold into the fresh market. However, the vast majority of processing is squeezing the grapefruit for juice. Because of the properties of the juice of red seedless grapefruit, including problems with color, the processing outlet is limited, and not currently profitable. Therefore, it is essential that the market for fresh red grapefruit be fostered and maintained. Any costs associated with this action would only be for the 11 week regulatory period. However, benefits from this action could stretch throughout the entire 33 week season. Even if this action was successful only in raising returns a few pennies a carton, when applied to 34 million cartons of red seedless grapefruit shipped to the fresh market, the benefits should more than outweigh the costs.

The limits that would be established under this action would be based on percentages applied to a handler's average week. This process was established by the committee because it was the most equitable. Also, all handlers would have access to loans and transfers. All handlers and growers would benefit from increased returns. The costs or benefits of this rule are not expected to be disproportionately more or less for small handlers or growers than for larger entities.

The committee discussed alternatives to this action. The committee discussed eliminating shipments of size 56 grapefruit all together. Several members expressed that there is a market for size 56 grapefruit. Members favored the percentage rule recommended because it would supply a sufficient quantity of small sizes should there be a demand for size 56. Therefore, the motion to eliminate size 56 was rejected. Another alternative discussed was to do nothing. However, the committee rejected this option, taking in account that returns would remain stagnant without action.

This rule would change the requirements under the Florida citrus marketing order. Handlers utilizing the flexibility of the loan and transfer aspects of this action would be required to submit a form to the committee. The rule would increase the reporting burden on approximately 80 handlers of red seedless grapefruit who would be taking about 0.03 hour to complete each report regarding allotment loans or transfers. The information collection requirements contained in this section have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and assigned OMB number 0581–0094. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule. However, red seedless grapefruit must meet the requirements as specified in the U.S. Standards for Grades of Florida Grapefruit (7 CFR 51.760 through 51.784) issued under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 through 1627).

In addition, the committee's meeting was widely publicized throughout the citrus industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the May 28, 1997, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A 15-day comment period is provided to allow interested persons to respond to this proposal. Fifteen days is deemed appropriate because this rule would need to be in place as soon as possible since handlers will begin shipping grapefruit in September. In addition, because of the nature of this rule, handlers need time to consider their allotment and how best to service their customers. Also, the industry has been discussing this issue for some time. The committee has kept the industry well informed on this issue. It has also been widely discussed at various industry and association meetings. Interested persons have had time to determine and express their positions. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 905

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements, Tangelos, Tangerines.

For the reasons set forth in the preamble, 7 CFR part 905 is proposed to be amended as follows:

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

1. The authority citation for 7 CFR Part 905 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. In § 905.306, paragraphs (a) and (b), the word ''During'' is removed and the words ''Except as otherwise provided in section 905.601, during'' are added in its place.

3. A new § 905.601 is added to read as follows:

§ 905.601 Red seedless grapefruit regulation 101.

The schedule below establishes the weekly percentages to be used to calculate each handler's weekly allotment of small sizes. If the minimum size in effect under section 905.306 for red seedless grapefruit is size 56, handlers can fill their allotment with size 56, size 48, or a combination of the two sizes such that the total of these shipments are within the established weekly limits. If the minimum size in effect under section 905.306 for red seedless grapefruit is 48, handlers can fill their allotment with size 48 red seedless grapefruit such that the total of these shipments are within the established weekly limits. The weekly percentages for sizes 48 and/or 56 red seedless grapefruit grown in Florida, which may be handled during the specified weeks are as follows:

Week	Weekly percentage
(a) 9/15/97 through 9/21/97	25
(b) 9/22/97 through 9/28/97	25
(c) 9/29/97 through 10/5/97	25
(d) 10/6/97 through 10/12/97	25
(e) 10/13/97 through 10/19/97	25
(f) 10/20/97 through 10/26/97	25
(g) 10/27/97 through 11/2/97	25
(h) 11/3/97 through 11/9/97	25
(i) 11/10/97 through 11/16/97	25
(j) 11/17/97 through 11/23/97	25
(k) 11/24/97 through 11/30/97	25

Dated: July 25, 1997.

Ronald L. Cioffi,

Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 97–20034 Filed 7–25–97; 1:13 pm]

BILLING CODE 3410–02–U

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 312

RIN 3064–AC01

Prevention of Deposit Shifting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Proposed rule; withdrawal.

SUMMARY: The FDIC is withdrawing a proposed rule to implement a statute prohibiting the shifting of deposits insured under the Savings Association Insurance Fund (SAIF) to deposits insured under the Bank Insurance Fund (BIF) for the purpose of evading the assessment rates applicable to SAIF deposits. The FDIC is taking this action in response to comments received on the proposed rule, which was published in the **Federal Register** on February 11, 1997.

DATES: The proposed rule is withdrawn July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph A. DiNuzzo, Counsel, (202) 898–7349, Legal Division; or George Hanc, Associate Director, Division of Research and Statistics, (202) 898–8719, Federal Deposit Insurance Corporation, Washington, D. C. 20429.

SUPPLEMENTARY INFORMATION:

I. The Funds Act and the Deposit Shifting Statute

A provision of the Deposit Insurance Funds Act of 1996 (Funds Act) requires the Comptroller of the Currency, the Board of Directors of the FDIC, the Board of Governors of the Federal Reserve System, and the Director of the Office of Thrift Supervision (federal banking agencies) to take ''appropriate actions'' to prevent insured depository institutions and holding companies

from ''facilitating or encouraging'' the shifting of deposits from SAIF-assessable deposits to BIF-assessable deposits for the purpose of evading the assessments applicable to SAIF-assessable deposits.[1] Pub. L. 104–208, 110 Stat. 3009–485, section 2703(d). This statutory prohibition on deposit shifting (the deposit shifting statute) expressly authorizes the FDIC to issue regulations, including regulations defining terms used in the statute, to prevent the shifting of deposits. The deposit shifting statute terminates on the earlier of December 31, 1999, or the date on which the last federally chartered savings association ceases to exist.

The Funds Act was enacted as part of the Economic Growth and Regulatory Paperwork Reduction Act of 1996, Pub. L. 104–208, 110 Stat. 3009–479 through 3009–498, sections 2701—2711, and became effective September 30, 1996. The Funds Act provided for the capitalization of the SAIF through a special assessment on all depository institutions that hold SAIF-assessable deposits.[2]

II. The Proposed Rule

In February 1997 the FDIC issued a proposed rule to implement the deposit shifting statute. 62 *FR* 6139 (Feb. 11, 1997). The proposed rule consisted of two basic provisions. The first reiterated the requirement in the statute that the respective federal banking agency deny applications and object to notices filed by depository institutions or depository institution holding companies if the purpose of the underlying transaction was to evade assessments payable on SAIF-assessable deposits. The second provision of the proposed rule would have established a presumption under which entrance and exit fees would be imposed upon depository institutions for deposits that are shifted from SAIF-assessable deposits to BIF-assessable deposits in violation of the deposit shifting statute.

III. Comments on the Proposed Rule

The comment period for the proposed rule closed on April 14, 1997. The FDIC received fifteen comments on the proposal. Nine of the comments were from industry trade groups, four from community banks, one from a bank holding company and one from a savings and loan holding company. Nine of the comments opposed the proposed rule. They argued, in essence, that a regulation is unnecessary given that SAIF is now capitalized and the assessment rate differential between BIF and SAIF institutions is not significant. Some who opposed the proposed rule contended that it is unworkably vague, particularly because it does not define key terms, such as ''deposit shifting'' and ''ordinary course of business.''

Of the national industry trade groups, one said that a regulation is not necessary and, instead, the agencies should just continue to monitor deposit shifting. Another commented that a regulation would not be necessary, but that the FDIC should consider issuing a policy statement to provide guidance to the industry. A third national trade group said the regulation would be an appropriate measure to enforce the deposit shifting statue. One state industry trade association voiced support for the proposed rule. Five others commented that a regulation was unnecessary.

The four community banks all commented that the regulation would be an appropriate means to enforce the statute. The bank holding company that commented detailed five areas of concern with the proposed rule, essentially citing a ''vagueness'' problem. The comment filed by the savings and loan holding company alleged, among other things, that the rule would be illegal under the U.S. Constitution and the Administrative Procedure Act.

IV. Withdrawal of the Proposed Rule

Based on a review of the comments and the FDIC's internal review of the applicable issues, the Board of Directors of the FDIC has decided to withdraw the proposed rule. The Board agrees with the majority of those who commented that the deposit shifting statute can and should be enforced on a case-by case basis and, thus, a regulation to implement and enforce the statute is unnecessary.

This decision is based on several factors: (1) The diminished differential between the assessments paid on BIF-assessable deposits and SAIF-assessable deposits; (2) the lack of evidence of any significant, widespread deposit shifting among depository institutions; (3) the regulatory burden that might result from the issuance of a final rule on deposit shifting; and (4) the ability of the FDIC and the other federal banking agencies to enforce the deposit shifting statute on a case-by-case basis through the monitoring of any such activity by reviewing quarterly financial reports and by conducting on-site examinations, if necessary.

The Board has decided, therefore, in coordination with the other federal banking agencies, that the deposit shifting statute should be enforced on a case-by-case basis. The FDIC, however, will monitor the effectiveness of this approach and, if necessary, reconsider in the future whether a regulation is needed to implement the deposit shifting statute.

By the order of the Board of Directors.

Dated at Washington, D.C., this 22nd day of July, 1997.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 97–19943 Filed 7–28–97; 8:45 am]

BILLING CODE 6714–01–P

[1] Although currently the range of risk-based assessments for BIF-assessable and SAIF-assessable deposits is the same, a higher assessment payable to the Financing Corporation must be paid on SAIF-assessable deposits. Thus, the overall assessment is higher for SAIF-assessable deposits than for BIF-assessable deposits.

[2] Pursuant to this requirement, the FDIC issued a final rule imposing a special assessment on institutions holding SAIF-assessable deposits in an amount sufficient to increase the SAIF reserve ratio to the designated reserve ratio of 1.25 percent as of October 1, 1996. 61 *FR* 53834 (Oct. 16, 1996), to be codified at 12 CFR 327.41.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–ASO–10]

Proposed Amendment to Class E Airspace; Anniston, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to amend the Class E airspace area at Anniston, AL. Global Positioning System (GPS) Runway (RWY) 3 and RWY 21 Standard Instrument Approach Procedures (SIAPs) have been developed for Talladega Municipal Airport, and a GPS RWY 20 SIAP has been developed for St. Clair County Airport. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate these SIAPs, and for Instrumental Flight Rules (IFR) operations at these airports and the Anniston Metropolitan Airport.

DATES: Comments must be received on or before September 9, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 97–ASO–10, Manager, Airspace Branch, ASO–520, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Assistant Chief Counsel for Southern Region, Room 550,

1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5586.

FOR FURTHER INFORMATION CONTACT:

Wade Carpenter, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5581.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–ASO–10.'' The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposed contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contract with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Class E airspace area at Anniston, AL. GPS RWY 3 and RWY 15 SIAPs have been developed for Talladega Municipal Airport, and a GPS RWY 20 SIAP has been developed for St. Clair County Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate these SIAPs, and for IFR operations at these airports and the Anniston Metropolitan Airport. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet above the surface of the earth.

* * * * *

ASO AL E5 Anniston, AL [Revised]

Anniston Metropolitan Airport, AL
(lat. 33°35′17″ N, long. 85°51′29″ W)
Talladega Municipal Airport
(lat. 33°34′12″ N, long. 86°03′04″ W)
St. Clair County Airport
(lat. 33°33′32″ N, long. 86°14′57″ W)

That airspace extending upward from 700 feet above the surface within a 12-mile radius of Anniston Metropolitan Airport and within a 9.5-mile radius of Talladega Municipal Airport and within a 11.5 mile radius of St. Clair County Airport, excluding that airspace within Restricted Area R–2101 when the restricted area is active.

* * * * *

Issued in College Park, Georgia, on July 15, 1997.

Wade T. Carpenter,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 97–19859 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 97N–0300]

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the packaging and labeling control provisions of the current good manufacturing practice (CGMP) regulations for human and veterinary drug products by limiting the application of special control procedures for the use of cut labeling to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. FDA is also proposing to permit the use of any automated technique,

including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment when cut labeling is used. This action is intended to protect consumers from labeling errors more likely to cause adverse health consequences, while eliminating the regulatory burden of applying the rule to labeling unlikely to reach or adversely affect consumers. This action is also intended to permit manufacturers to use a broader range of error prevention and labeling control techniques.

DATES: Comments by October 27, 1997. FDA proposes that any final rule that may issue based on this proposal become effective 6 months after its date of publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville MD 20857.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), 5600 Fishers Lane, Rockville, MD 20857, 301–594–5621 (Internet electronic mail: kuchenbergt@cder.fda.gov); or

Paul J. Motise, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1089 (Internet electronic mail: motise@cder.fda.gov).

SUPPLEMENTARY INFORMATION:

I. Background

Persistent problems with drug product mislabeling and subsequent recalls in the late 1980's led FDA to review labeling procedures and product recalls. The review identified gang-printed or cut labeling as a leading cause of labeling mixups. Gang-printed labeling is defined in 21 CFR 210.3(b)(22) as labeling derived from a sheet of material on which more than one item of labeling is printed. Each sheet includes labeling for a variety of products and, because of this, labeling for individual drug products must be ''cut'' or separated from the labeling for other products. Cut labeling for individual drug products is commonly placed in separate stacks before being transported to packaging and labeling lines for application to appropriate products. FDA found that stacks of labeling of similar size, shape, and color could easily be intermixed and, if the error was not detected by the printer or manufacturer, incorrect labeling could be applied and a mislabeled drug product distributed.

To reduce the frequency and likelihood of such mislabeling, FDA, in the **Federal Register** of August 3, 1993 (58 FR 41348), amended the packaging and labeling control provisions of the CGMP regulations in part 211 (21 CFR part 211) to provide specific conditions for the use of all gang-printed or cut labeling (hereinafter referred to as the 1993 final rule). Under § 211.122(g), packaging and labeling operations must use one of three special control features if cut labeling is used. Packaging and labeling lines must be dedicated to each different strength of each different drug product, appropriate electronic or electromechanical equipment must be used to conduct a 100-percent examination for correct labeling during or after completion of finishing operations, or, where labeling is hand-applied, a 100-percent visual inspection must be conducted by one person and independently verified by a second person. Appropriate electronic or electromechanical equipment typically consists of systems that scan identity codes printed on the labeling. If the wrong code is detected, the incorrect labeling is ejected from the labeling line.

To further limit the potential for mislabeling, FDA also required written procedures for the identification and handling of filled drug product containers not immediately labeled (§ 211.130(b)). FDA also amended § 211.125(c) to exempt manufacturers that use automated 100-percent examination for correct labeling from the label reconciliation requirements.

The 1993 final rule applied to all types of labeling including product inserts, multiunit containers packaged in individual containers, and shipping containers.

In May 1994, FDA received two citizen petitions from several trade associations requesting that the agency extend the effective date of the rule and reopen the administrative record to receive additional comments on the application of § 211.122(g) to items of labeling other than the immediate container label. The petitions stated that additional time was needed to obtain, install, or validate equipment necessary to comply with the rule. The citizen petitions also contended that the final rule inappropriately expanded the scope of § 211.122(g) from immediate container labels to all drug product labeling.

In the **Federal Register** of August 2, 1994 (59 FR 39255), FDA extended the compliance date for § 211.122(g) as it applies to labeling other than immediate container labels, and opened the administrative record through October 4, 1994, for comments on the scope of § 211.122(g). All other provisions of the final rule became effective on August 3, 1994. FDA further extended the compliance date to August 2, 1996, in the **Federal Register** of April 28, 1995 (60 FR 20897), and to August 1, 1997, in the **Federal Register** of July 19, 1996 (61 FR 37679).

Elsewhere in this issue of the **Federal Register**, FDA is announcing a continuation of the partial extension of the compliance date until the effective date of the regulation finalizing this proposed rule.

FDA received 14 comments during the extended comment period. Those comments that addressed the scope of § 211.122(g) are discussed below:

Concerning the question of whether § 211.122(g) should be applied to items of labeling other than the immediate container label, most comments favored restricting application of the regulation either to immediate container labels or to some category or subset of overall product ''labeling.'' Several comments requested that manual differentiation by size, shape, and color as well as other validated labeling control methods be added to the list of special control procedures listed in § 211.122(g). One comment asserted that specifying the use of electronic or electromechanical methods as a special control procedure unnecessarily limits the options of firms packaging pharmaceuticals. A number of comments stated that, with appropriate controls, the use of size, shape, or color differentiation as a manual labeling control measure is adequate to prevent labeling mixups. A number of comments asked for clarification as to which types of cut labeling would require the use of an automated verification system. Some comments requested exemptions for specific labeling. One comment requested that hand-labeling operations be specifically excluded from the requirement for electronic inspection, regardless of the volume of the manufacturing operation, if labeling is inspected manually. Another comment recommended procedures to be used when cut labeling is applied to dosage-form packages assembled in stages.

In light of comments received during the extended comment period, FDA held a number of meetings with representatives of the labeling industry and others to examine control options available through current technology.

After evaluating the comments, reviewing the recall data, and surveying packaging and labeling control technology, FDA has determined that the scope of § 211.122(g) should be

narrowed and the permissible control procedures expanded. FDA is proposing to limit the scope of the cut labeling provision to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. FDA is also proposing to expand the permissible control procedures to include the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

II. Description of the Proposed Rule

A. Scope

The first sentence of current § 211.122(g) states: ''If cut labeling is used, packaging and labeling operations shall include one of the following special control procedures''.

FDA is proposing to limit the scope of § 211.122(g) by revising this sentence to state: ''If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures''.

FDA's main concern in proposing controls for cut labeling is to reduce the public health and safety risk stemming from drug product labeling mixups. The petitions and comments on the scope of § 211.122(g) asserted that the economic burden on industry would be great if the provision applied to all labeling, and questioned whether including such types of labeling as shipping cartons, that are unlikely to be read by consumers, would provide any significant additional protection to public health and safety.

FDA has examined these comments and other information and agrees that the greater the likelihood that consumers will read incorrect labeling information, the greater the danger that the drug product will be used according to the mislabeled instructions. Thus, the immediate container label poses the most obvious threat. In addition, individual unit carton labeling could pose an equal danger because it is the outermost container in which a drug product is commonly marketed at retail and many consumers read this labeling when deciding whether to purchase a product. Moreover, because the individual unit carton labeling may be in a larger type or otherwise easier to read than the immediate container label, consumers may keep the carton and refer to it when using the drug product. A similar concern applies to multiunit cartons containing immediate containers that are not packaged in individual unit cartons (e.g., sterile dosage forms in tray packs in which immediate containers lack unit cartons), because consumers and health professionals are more likely to rely on labeling on the outer multiunit container than to examine the labeling on the individual drug product immediate containers. In deciding whether to limit the scope of the labeling control provisions, FDA reviewed recall data to determine the danger to consumers from errors in different types of drug product labeling.[1] This examination indicated that there have been Class I and Class II recalls involving immediate containers, individual unit cartons containing the drug product in its immediate container, and multiunit cartons containing immediate containers that are not packaged in individual unit cartons. Recalls due to the use of the wrong inserts or outserts (printed information about a drug product attached to the exterior of the product) and recalls of multiunit or shelf-pack containers holding unit cartons, shipping or intermediate containers, and shipping cases have all been designated as Class III recalls, i.e., situations in which the labeling error is generally not likely to cause adverse health consequences.

Therefore, FDA is proposing that the control procedures specified in § 211.122(g) apply only to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. This action is intended to protect consumers from labeling errors that are more likely to cause adverse health consequences, while eliminating the regulatory burden of applying the rule to labeling unlikely to reach or adversely affect consumers. The proposal is also intended to eliminate any confusion about the scope of the cut labeling control provisions and allow an additional opportunity for public comment.

Although a number of types of labeling would not be subject to this proposed rule, it is important to note that any labeling mixup can result in a misbranded drug product. FDA encourages manufacturers to take steps to protect the integrity of their labeling operations. Although not proposed in this rulemaking, FDA encourages firms to: (1) Convert all articles of cut labeling to roll labeling where possible (such as the use of roll inserts or roll label/insert combinations); (2) use online printing methods; or (3) adopt 100-percent automated verification systems for all items of cut labeling.

B. Special Control Procedures

Under § 211.122(g)(1), (g)(2), and (g)(3), packaging and labeling operations must include one of the following special control procedures when cut labeling is used: (1) Dedication of labeling and packaging lines to each different strength of each different drug product; (2) use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or (3) use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling.

FDA is proposing to add a fourth special control procedure at § 211.122(g)(4): ''Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.'' FDA is proposing this additional control procedure because the agency believes that a number of other automated techniques will also physically prevent incorrect labeling from being processed by packaging and labeling equipment, and would provide manufacturers with the widest possible latitude in selecting appropriate labeling control technologies. A labeling control method using size and shape as part of an automated technique that prevents incorrect labeling from being processed by labeling and packaging lines provides the same labeling control protection, through prevention, as do the other special control procedures through surveillance or dedication of labeling and packaging lines. An acceptable automated technique would allow labeling and packaging operations to operate only if correct labeling unique to a given product (e.g., a specific size) is used.

FDA notes, however, that nonautomated (i.e., manual) differentiation of size and shape as a labeling control does not provide adequate protection from labeling mixups. It is the increased opportunity

[1] Unless ordered by a court, a drug recall is a voluntary action whereby manufacturers remove from the market drugs that are found by FDA to be marketed in violation of laws administered by the agency.

Under FDA's current policy, the agency assigns a numerical designation to each product recall to indicate the relative degree of hazard presented by the product being recalled. A Class I recall involves the greatest potential health threat and a Class III recall involves the least serious health threat.

for human error afforded by the process of cutting, sorting, and subsequent handling of different items of labeling from gang-printed materials that has caused labeling mixups and recalls. One of the goals of this proposed rulemaking is to reduce the likelihood for such human error through the use of automated labeling control systems.

III. Environmental Impact

The agency has determined under 21 CFR 25.24 (a) (10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (2 U.S.C. 1532). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order.

The proposed rule substantially reduces the scope of the 1993 final rule, which applied to all cut labeling, so that the proposed rule only applies to cut labeling for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. This proposed rule also increases flexibility for firms selecting special labeling control procedures by adding a provision for the use of any automated technique, including differentiation by size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment. Therefore this proposed rule is expected to have a positive economic impact on drug manufacturers that would otherwise be subject to the more stringent requirements under current regulations.

Mislabeled drug products may pose a threat to public health, lead to extremely costly product recalls, and create significant product liability. As a result, FDA believes that a large number of firms already use the labeling control procedures proposed in this rulemaking. The agency concludes that the proposed rule is not a major rule as defined in Executive Order 12866 because the labeling control revisions significantly reduce the scope of the current rule and provide manufacturers with greater flexibility in selecting special control procedures if cut labeling is used. Further, the agency certifies that the proposed rule is not expected to have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act.

The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). Because this proposed rule will not impose a cost of $100 million or more on any governmental entity or the private sector, no budgetary impact statement is required.

V. Request for Comments

Interested persons may, on or before October 27, 1997, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 211 be amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: Secs. 201, 501, 502, 505, 506, 507, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374).

2. Section 211.122 is amended by revising the introductory text of paragraph (g) and by adding new paragraph (g)(4) to read as follows:

§ 211.122 Materials examination and usage criteria.

* * * * *

(g) If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures:

* * * * *

(4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

* * * * *

Dated: July 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–19817 Filed 7-28-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AI84

Grants to States for Construction or Acquisition of State Home Facilities

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the ''Medical'' regulations in 38 CFR part 17 regarding applications for grants to States for the construction or acquisition of State home facilities. VA awards grants based on a priority ranking system. Usually, the higher priority applications deplete the available funding to the extent that the lowest ranking application to be offered funding is offered only a partial grant. It is proposed that if the lowest ranking grant application receives only a partial grant in a fiscal year and if such grant award is partial solely because VA has insufficient funds for a full grant, the application would be placed at the top of the list within its priority group for the next fiscal year. Often applicants are hesitant to accept a partial grant because of the uncertainty of receiving an additional grant the next fiscal year. It appears that the adoption of the proposal would encourage States to accept a partial grant by creating the likelihood that the State would receive an additional grant in the subsequent

fiscal year. Accordingly, this would help ensure that VA would be able to award grants to higher priority applicants that might otherwise reject partial funding.

Also, it is proposed that the applicant receiving partial funding and receiving priority as proposed would not be required to submit a second application for additional funds in the subsequent fiscal year, but could be required to update information already submitted. It appears that the first application would normally be adequate because the grant award in the second fiscal year would be for the same project which received the partial grant award.

Further, under the proposal, the total amount awarded for the application could not exceed 65 percent of the total cost of the project as determined at the time of the second grant award for that grant application. This is consistent with the statutory requirement that limits grant awards to no more than 65 percent of the estimated cost of construction or acquisition.

DATES: Comments must be received on or before September 29, 1997.

ADDRESSES: Mail or hand deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1154, Washington, DC 20420. Comments should indicate that they are submitted in response to ''RIN 2900–AI84.'' All written comments received will be available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Ms. Kathleen Greve, Geriatrics and Extended Care Strategic Healthcare Group, (202) 273–8534.

SUPPLEMENTARY INFORMATION: The Secretary hereby certifies that the adoption of this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The rule would affect grants to States and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rule would be exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance program number for this document is 64.005.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: July 17, 1997.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 17 is proposed to be amended as set forth below:

PART 17—MEDICAL

1. The authority citation for part 17 continues to read as follow:

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

2. In § 17.212, paragraph (d) is added immediately before the section authority citation following paragraph (c) to read as follows:

§ 17.212 Scope of grants program.

* * * * *

(d)(1) Notwithstanding paragraph (c) of this section and the provisions for ranking projects within a priority group in § 17.213(c)(3)(i), the Secretary shall give an application first priority within the priority group to which it is assigned on the list of projects established under § 17.213(d) for the next fiscal year if:

(i) the State has accepted a grant for that application as of August 15 of the current fiscal year that is less than the amount that the Secretary would have awarded if VA had had sufficient grant funds to award the grant in such amount in that fiscal year; and

(ii) the application is the lowest ranking application on the priority list for the current fiscal year for which grant funds are available as of August 15 of that year.

(2) The Secretary shall not require a State to submit a second grant application for a project which receives priority under paragraph (1) of this section but may require the State to update information already submitted in the application for the project. The Secretary shall determine the amount of a second grant at the time of the award of that grant. In no case shall the total amount awarded for the application exceed 65 percent of the total cost of the project as determined at the time of the second grant award for that grant application.

* * * * *

[FR Doc. 97–19855 Filed 7–28–97; 8:45 am]

BILLING CODE 8320–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN189–1–9730(b); TN194–1–9731(b); TN198–1–9732(b); FRL–5859–6]

Approval of Revisions to the Tennessee SIP Regarding Prevention of Significant Deterioration and Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is approving miscellaneous revisions to the Tennessee State Implementation Plan (SIP) regarding prevention of significant deterioration (PSD) and volatile organic compounds (VOC). The revisions to the PSD regulation add an additional supplement to the EPA ''Guideline on Air Quality Models''. The revisions to the VOC regulation make minor changes to the regulation for the manufacture of high-density polyethylene, polypropylene and polystyrene resins and to the regulation containing test methods and compliance procedures for VOC sources. In the final rules section of this **Federal Register**, the EPA is approving the submitted chapter in its entirety as a direct-final rule without prior proposal because the EPA views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by August 28, 1997.

ADDRESSES: Written comments on this action should be addressed to William Denman at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW,

Atlanta, Georgia 30303. Copies of documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference files TN189–1–9730, TN194–1–9731, and TN198–1–9732. The Region 4 office may have additional background documents not available at the other locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460

Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. William Denman 404/562–9030

Tennessee Department of Environment and Conservation, Division of Air Pollution Control, 9th Floor L & C Annex, 401 Church Street, Nashville, Tennessee 37243–1531.

FOR FURTHER INFORMATION CONTACT: William Denman at 404/562–9030.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: July 3, 1997.

Michael V. Peyton,

Acting Regional Administrator.

[FR Doc. 97–19938 Filed 7–28–97; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 384

[Docket No. R–166]

RIN 2133–AB26

Criteria for Granting Waivers of Requirement for Exclusive U.S.-Flag Carriage of Certain Export Cargoes

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Withdrawal of advance notice of proposed rulemaking.

SUMMARY: The Maritime Administration (MARAD) is withdrawing its rulemaking, initiated through an advance notice of proposed rulemaking (ANPRM) published on October 28, 1996, soliciting public comment on whether it should amend its existing criteria and methodologies for granting waivers of the requirement for U.S.-flag vessel carriage of cargo covered by Public Resolution 17 (PR17), 33rd Congress. In administering this law, MARAD has been following a policy for granting waivers which was published in 1959.

FOR FURTHER INFORMATION CONTACT: Murray Bloom, Chief, Division of Maritime Assistance Programs, Office of the Chief Counsel, Telephone (202) 366–5320.

SUPPLEMENTARY INFORMATION: On October 28, 1996, MARAD published an ANPRM (61 FR 55614) setting forth its policy for granting waivers of the requirement for exclusive U.S.-flag carriage of certain cargo covered by PR17 (46 App U.S.C. 1241–1), soliciting public comment on whether it should amend its criteria that have been in effect since 1959, and if so, how the criteria should be changed. In a subsequent notice published on December 24, 1996 (61 FR 67764), MARAD extended the original 60 day comment period for 45 days, and posed 12 questions involving whether MARAD should actually issue a rule that states the objectives and the procedures that will guide the waiver process, as well as the merits, respectively, of various specified procedures. After the receipt and careful review of comments, MARAD held a public forum on May 29, 1997, which allowed interested parties to present oral and written comments to MARAD and officials of the Export-Import Bank of the United States, which administers a program granting credits (loans) with respect to agricultural or other U.S. products for export, that is within the scope of PR17.

Based on the positions enunciated by ocean carriers and shippers with divergent interests, MARAD concluded, with the concurrence of the Export-Import Bank, that the promulgation of discrete regulations of general applicability is not feasible. Therefore, MARAD will continue to grant waivers through case-by-case determinations. Accordingly, on July 2,1997, MARAD published (62 FR 35881) a revised policy statement that applies to credits of the Export-Import Bank.

Dated: July 23, 1997.

By Order of the Acting Maritime Administrator.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. 97–19843 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–81–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 96–111; CC Docket No. 93–23; FCC 97–252]

Non-U.S.-Licensed Satellites Providing Domestic and International Service in the United States

ACTION: Proposed rule.

SUMMARY: With this Further Notice of Proposed Rulemaking, the Commission seeks additional comment on a framework to allow non-U.S.-licensed satellites to provide domestic and international satellite services in the United States. The Commission tentatively concludes that the public interest requires adoption of uniform standards to determine whether a non-U.S. satellite system should be permitted to serve the United States. The Commission aims to promote greater market access, to foster fair competition, and to ensure lower prices, better service, and more innovative service offerings for U.S. users and competitors. This Further Notice of Proposed Rulemaking contains proposed or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA). It has been submitted to the Office of Management and Budget (OMB) for review under the PRA. OMB, the general public, and other Federal agencies are invited to comment on the proposed or modified information collections contained in this proceeding.

DATES: Comments may be filed no later than August 21, 1997. Reply Comments may be filed no later than September 5, 1997. Written comments by the public on the proposed and/or modified information collections are due September 29, 1997. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed and/or modified information collections on or before September 29, 1997.

ADDRESSES: Office of the Secretary, Room 222, Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 234, 1919 M Street, NW., Washington, DC 20554, or via the Internet to jboley@fcc.gov, and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725—17th Street, NW.,

Washington, DC 20503 or via the Internet to fain__t@al.eop.gov.

FOR FURTHER INFORMATION CONTACT: Fern Jarmulnek at (202) 418–0751, William Kirsch at (202) 418–0764, or Robert Calaff at (202) 418–0431 of the International Bureau. For additional information concerning the information collections contained in this Further Notice of Proposed Rulemaking, contact Judy Boley at (202) 418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Further Notice of Proposed Rulemaking in IB Docket No. 96–111; CC Docket No. 93–23; FCC 97–252, adopted July 16, 1997 and released July 18, 1997. The complete text of this Further Notice of Proposed Rulemaking is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC, and also may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW, Washington, DC 20036, telephone: 202–857–3800, facsimile: 202–857–3805.

This Further Notice of Proposed Rulemaking contains either a proposed or modified information collection. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collections contained in this Further Notice of Proposed Rulemaking, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due on or before August 21, 1997; OMB notification of action is due September 29, 1997. Comments should address: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

The modifications to approve collections have been submitted to the Office of Management and Budget for review under Section 3507(d) of the Paperwork Reduction Act (44 U.S.C. 3507(d)). For copies of the submissions contact Judy Boley at (202) 418–0214. A copy of any comments filed with the Office of Management and Budget should also be sent to the following address at the Commission: Federal Communications Commission, Performance Evaluation and Records Management Branch, Room 234, Paperwork Reduction Project, OMB No. 3060–0678, Washington, DC 20554. For further information contact Judy Boley, (202) 418–0214.

OMB Approval Number: 3060–0678.

Type of Review: Revision of existing collections.

Title: Rules and Regulations for Satellite Applications and Licensing Procedures.

(**Note:** title name change)

Form Number: 312.

Respondents: Businesses or other for profit, including small businesses, governments.

Number of Respondents: 1,310.

Estimated Time Per Response: The Commission estimates that all respondents will hire an attorney or legal assistant to complete the form. The time to retain these services is 2 hours per respondent.

Total Annual Burden: 2,620 hours.

Estimated Costs Per Respondent: This includes the charges for hiring an attorney, legal assistant, or engineer at $150 an hour to complete the submissions. The estimated average time to complete the Form 312 is 10 hours per response. The estimated average time to complete space station submissions is 20 hours per response. The estimated average time for prepare submissions using non-U.S. licensed satellites is 22 hours per response. The estimated average time to complete the ASIA submission is 24 hours per response. Earth station submissions: $1935. ($1500 for Form 312; $375 remainder of application; $60 for outside hire). Space station submissions: $4560 ($1500 for Form 312; $3000 for remainder of submission; $60 for outside hire). ASIA submissions: $3,660 ($3,600 for submission; $60 for outside hire). Non-U.S. licensed satellite filings: $3,360 ($3,300 for submissions; $60 for outside hire). Fee amounts vary by type of service and application. Total fee estimates for industry: $5,814,347.00

Needs and Uses: In accordance with the Communications Act, the information collected will be used by the Commission in evaluating applications requesting authority to operate pursuant to Part 25 of the Commission's rules. The information will be used to determine the legal, technical, and financial ability of the applicants and will assist the Commission in determining whether grant of such authorizations are in the public interest.

Summary of Further Notice of Proposed Rulemaking

1. With this Further Notice of Proposed Rulemaking, the Commission seeks additional comment on a framework to allow non-U.S. licensed satellites to provide service domestic and international satellite services in the United States. These issues were raised initially in a Notice of Proposed Rulemaking in the Domestic International Consolidation (*DISCO II*) proceeding issued on May 14, 1996, 61 FR 32398 (June 24, 1996). In that Notice of Proposed Rulemaking, the Commission proposed to apply an ''effective competitive opportunities'' for satellites or ''ECO-Sat'' test to determine whether U.S. satellites have access to a foreign market before allowing a satellite licensed by that foreign country to serve the United States.

2. In light of the recent conclusion of a World Trade Organization Agreement (WTO) on Basic Telecommunications Services (''Agreement''), this Further Notice of Proposed Rulemaking revisits the *DISCO II* proposal, and asks for comment on how best to open U.S. markets in a manner consistent with our overriding goal of promoting a competitive satellite market in the United States. The Commission seeks comment on whether, and to what extent, the *DISCO II* proposals should be changed both with respect to countries and services covered by the Agreement and those that are not. In particular, the Commission proposes (1) to establish a presumption that no ECO-Sat analysis is required in evaluating whether to permit satellites licensed by WTO members to provide services covered by the U.S. schedule of commitments under the Agreement (''covered services'') within the United States and between the United States and other WTO members; (2) to retain the proposed ECO-Sat test for non-WTO members, intergovernmental organizations, and services for which the United States has taken an exemption from most-favored-nation obligations under the Agreement (''non-covered services''); and (3) to consider whether grant of an application to access a non-U.S. licensed satellite will otherwise serve the public interest, convenience, and necessity.

3. In addition, this Further Notice of Proposed Rulemaking proposes that non-U.S. licensed satellites be eligible to be participate in a U.S. satellite processing round either by filing an earth station application or a letter of intent to participate by the cut-off date for consideration in that round. The

Commission does not propose to require participation in U.S. processing rounds as a prerequisite to access to the U.S. market. Rather, systems coordinated under International Telecommunications Union (ITU) procedures seeking coordination would be accommodated through earth station licensing to the extent possible.

4. In this Further Notice of Proposed Rulemaking, the Commission tentatively concludes that the public interest requires that the Commission adopt uniform standards to determine whether a non-U.S. satellite system should be permitted to serve the United States. In proposing these standards, the Commission seeks to foster efficient and innovative satellite communications services for U.S. users through fair competition among multiple service providers, including non-U.S. service providers. In recognition of the liberalization of the global telecommunications market under the WTO Basic Telecom Agreement, the Commission proposes to rely on competitive market forces rather than an analysis of effective competitive opportunities abroad in evaluating requests to serve the United States using WTO member satellite systems. To promote competition where the WTO Basic Telecom Agreement does not apply, the Commission proposes to apply an ECO-Sat analysis where requests to serve the United States involve non-WTO satellite systems, IGO satellite systems, or services exempt from most-favored-nation obligations under the WTO Basic Telecom Agreement. In proposing this framework, the Commission aims to promote greater market access, to foster fair competition, and to ensure lower prices, better service, and more innovative service offerings for U.S. users and competitors. The Commission may condition or deny authorizations based on other important public interest considerations. These include: spectrum availability and technical coordination, compliance with Commission rules and procedures, and compliance with foreign ownership rules. The Commission tentatively concludes that requiring applicants to provide the same information the Commission requires for U.S. systems is consistent with the General Agreement on Trade in Services (GATS) obligations. The Commission also seeks comment, on what, if any, additional changes should be made to the earth station application form (Form 312).

Procedural Issues

5. As required by section 603 of the Regulatory Flexibility Act, the Commission has prepared an Initial Regulatory Flexibility Analysis (''IRFA'') of the expected impact on small entities of the proposals suggested in this document. The IRFA is set forth in below. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of this Further Notice of Proposed Rulemaking, but they must have a separate and distinct heading designating them as responses to the Initial Regulatory Flexibility Analysis. The Secretary shall send a copy of this Further Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

6. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before August 21, 1997 and reply comments on or before September 5, 1997. To file formally in this proceeding, you must file an original and four copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you should file five additional copies. Send comments and reply comments to the Office of the Secretary, Room 222, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the Federal Communications Commission, Reference Center, Room 239, 1919 M Street NW., Washington, DC 20554.

7. Written comments by the public on the proposed and/or modified information collections are due to Commission on or before September 29, 1997. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Performance Evaluation and Records Management Branch, Room 234, 1919 M Street, NW., Washington, DC 20554, or via the Internet to jboley@fcc.gov and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725 17th Street, NW., Washington, DC 20503 or via the Internet to fain__t@al.eop.gov.

Note: OMB is required to make a decision concerning the modified collection of information contained in this Further Notice of Proposed Rulemaking between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

8. This is a permit but disclose notice and comment rulemaking proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's rules. *See generally* 47 CFR 1.1202, 1.1203, and 1.1206(a).

Ordering Clauses

9. Accordingly, it is ordered that pursuant to the authority contained in Sections 1, 4(i), 303(r), 308, 309, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 303, and 308, notice is hereby given of our intent to adopt the policies and rules set forth in this Further Notice of Proposed Rulemaking and that comment is sought on all the proposals in this Further Notice of Proposed Rulemaking.

10. It is further ordered that the Secretary shall send a copy of this Further Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Initial Regulatory Flexibility Analysis

A. Reason for Action

11. In this proceeding the Commission seeks to solicit comments and develop a record on the proposed policies and rules to allow non-U.S. licensed satellite systems and satellite transmissions originating outside of the U.S. to enter the U.S. market and to continue licensing receive-only earth stations operating with non-U.S. satellite systems. These proposed rules are designed in large part to promote competition and enhance customer service and options throughout the United States and the world.

B. Objective

12. The Commission seeks to establish standard rules and procedures to regulate foreign entry into the U.S. satellite services market in order to promote competition, prevent anti-competitive conduct in the market for international communications services, and foster open communications markets around the world.

C. Legal Basis

13. The legal basis of this action is found in Sections 303 and 308(c) of the Communications Act of 1934, 47 U.S.C. 303 and 308(c).

D. Reporting, Recordkeeping and Other Compliance Requirements

14. We propose to require that earth stations and other entities working in

conjunction with non-U.S. satellite systems and foreign satellite service providers file certain information regarding the foreign service, markets, and satellite systems. This is not estimated to be a significant economic burden for these entities.

E. Federal Rules That Overlap, Duplicate or Conflict With These Rules

15. None.

F. Description, Potential Impact and Number of Small Facilities Affected

16. The proposed rules would apply to all earth stations or service providers (including small entities) that seek authorization under Part 25 and Part 100 of the Commission's rules to operate with a non-U.S. licensed satellite. These proposals are intended to ensure that U.S. satellite systems can compete effectively in international markets and that competition in the United States is maximally enhanced. Copies of this Further Notice of Proposed Rulemaking will be sent to the Chief Counsel for Advocacy of the Small Business Administration.

G. Any Significant Alternative Minimizing Impact on Small Entities Consistent With Stated Objectives

17. The Further Notice of Proposed Rulemaking solicits comment on other alternatives to achieve the Commission's objectives.

List of Subjects in 47 CFR Part 25

Satellites.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–20016 Filed 7–28–97; 8:45 am]

BILLING CODE 6712–01–U

DEPARTMENT OF DEFENSE

48 CFR Part 236

[DFARS Case 97–D015]

Defense Federal Acquisition Regulation Supplement; Architect-Engineer Selection process

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: The Director of Defense Procurement is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to streamline the process for selection of firms for architect-engineer contracts.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before September 29, 1997, to be considered in the formulation of the final rule.

ADDRESSES: Interested parties should submit written comments to: Defense Acquisition Regulations Council, Attn: Ms. Amy Williams, PDUSD (A&T) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington DC 20301–3062. Telefax number (703) 602–0350. Please cite DFARS Case 97–D015 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT:

Ms. Amy Williams, (703) 602–0131.

SUPPLEMENTARY INFORMATION:

A. Background

This rule proposes revisions to DFARS 236.602 to streamline the process for selection of firms for architect-engineer contracts. The rule eliminates requirements for formal constitution and minimum size of preselection boards; eliminates special approval requirements for selection of firms for contracts exceeding $500,000; and changes the criteria for inclusion of firms on a preselection list from ''the maximum practicable number of qualified firms'' to ''the qualified firms that have a reasonable chance of being considered as most highly qualified by the selection board.''

B. Regulatory Flexibility Act

This proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule streamlines, but does not significantly alter, the process for selection of firms for architect-engineer contracts. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS subpart also will be considered in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 97–D015 in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply, because this proposed rule does not impose any information collection requirements that require approval of the Office of Management and Budget under 44 U.S.C. 3401, *et seq.*

List of Subjects in 48 CFR Part 236

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR part 236 is proposed to be amended as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 236—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

2. Section 236.602–2 is revised to read as follows:

§ 236.602–2 Evaluation boards

(a) Preselection boards may be used to identify to the selection board the qualified firms that have a reasonable chance of being considered as most highly qualified by the selection board.

3. Section 236–4 is revised to read as follows:

§ 236.602–4 Selection authority.

(a) The selection authority shall be at a level appropriate for the dollar value and nature of the proposed contract.

(c) A finding that some of the firms on the selection report are unqualified does not preclude approval of the report, provided that a minimum of three most highly qualified firms remains. The reasons for finding a firm or firms unqualified must be recorded.

[FR Doc. 97–19906 Filed 7–28–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 072297A]

RIN: 0648-AJ71

Amendment 49 to the Fishery Management Plan for Groundfish Fishery of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce

ACTION: Notice of availability of an amendment to a fishery management plan; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) has submitted Amendment 49 to the Fishery Management Plan for Groundfish of the Gulf of Alaska for Secretarial review. Amendment 49 would require all vessels fishing for groundfish in the Gulf of Alaska (GOA) to retain all

pollock and Pacific cod beginning January 1, 1998, and all shallow-water flatfish beginning January 1, 2003. Amendment 49 also would establish minimum utilization standards for all at-sea processors—for pollock and Pacific cod beginning January 1, 1998, and for shallow-water flatfish beginning January 1, 2003. Comments from the public are requested.

DATES: Comments on Amendment 49 must be submitted on or before September 29, 1997.

ADDRESSES: Comments on Amendment 49 should be submitted to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802-1668, Attn: Lori Gravel, or delivered to the Federal Building, 709 West 9th. Street, Juneau, AK. Copies of Amendment 49 and the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis prepared for the amendment are available from NMFS at the above address, or by calling the Alaska Region, NMFS, at 907–586–7228.

FOR FURTHER INFORMATION CONTACT: Kent Lind, 907-586-7228.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires that each Regional Fishery Management Council submit any fishery management plan (FMP) or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or amendment, immediately publish a document announcing that the FMP or amendment is available for public review and comment. NMFS will consider the public comments received during the comment period in determining whether to approve the FMP or amendment.

Amendment 49 is the result of over 3 years of specific discussions and analyses of alternative solutions to the discard problem occurring in the groundfish fisheries off Alaska. The expressed intent of the Council is to implement a program that ''would provide an incentive for fishermen to avoid unwanted catch, increase utilization of fish that are taken, and thus reduce discards of whole fish.'' While such discards are counted against the overall total allowable catch established for each species and do not represent a direct biological concern, they do represent foregone harvest opportunities for other fishing operations which might otherwise target and utilize those fish. In addition, high levels of discards represent an important social policy issue, which the fishing industry and the Council feel the necessity to address.

In September 1996, after extensive debate and public testimony, the Council adopted an Improved Retention/Improved Utilization (IR/IU) program as Amendment 49 to the FMP for the Groundfish Fishery in the Bering Sea and Aleutian Islands Area (BSAI). A proposed rule to implement Amendment 49 in the BSAI was published in the **Federal Register** on June 26, 1997 (62 FR 34429). In June 1997, the Council adopted a parallel IR/IU program as Amendment 49 for the GOA. The retention requirement adopted by the Council for the GOA would require full retention of pollock and Pacific cod beginning January 1, 1998, and full retention of shallow-water flatfish beginning January 1, 2003. The utilization requirement adopted by the Council would require that the above species either be (1) processed at sea subject to minimum recovery rates and/or requirements to be specified by regulation, or (2) delivered in their entirety to onshore processing plants for which similar minimum requirements are to be implemented through state regulations.

NMFS will consider the public comments received during the comment period in determining whether to approve Amendment 49. A proposed rule to implement Amendment 49 is scheduled to be published within 15 days of this document.

Dated: July 23, 1997.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 97–19847 Filed 7-28-97; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register

Vol. 62, No. 145

Tuesday, July 29, 1997

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Center for Nutrition Policy and Promotion; Agency Information Collection Activities: Proposed Collection; Comment Request—Adapting the Food Guide Pyramid for Young Children

AGENCY: Center for Nutrition Policy and Promotion, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on a proposed information collection. This notice announces the Center for Nutrition Policy and Promotion's intention to request the Office of Management and Budget approval of the information collection instruments to be used during consumer research with focus groups of parents of young children and day care personnel caring for young children to identify key issues of concern for nutrition education for young children two to six years of age. Approval is also requested for an additional collection instrument to be used during consumer research to test prototype nutrition promotion products and materials produced by USDA. The information collected will be used in adapting the Food Guide Pyramid for young children.

DATES: Written comments on this notice must be submitted on or before September 29, 1997.

ADDRESSES: Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the propose collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Bill Layden, Nutrition Promotion Staff Director, Center for Nutrition Policy and Promotion, U.S. Department of Agriculture, 1120 20th Street, NW, Suite 200 North Lobby, Washington, DC 20036.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION: Requests for additional information should be directed to Kay Loughrey, (202) 606–4835.

SUPPLEMENTARY INFORMATION:

Title: Adapting the Food Guide Pyramid for Young Children.

OMB Number: Not assigned yet.

Expiration Date: Not applicable.

Type of Request: New collection of information.

Abstract: The U.S. Department of Agriculture's Food Guide, expressed in the Food Guide Pyramid, is designed to help all healthy American two years of age and over implement the Dietary Guidelines for Americans. Adaptation of the Food Guide Pyramid for young children is key to helping them apply the Dietary Guidelines to improve their diets. This study involves six focus group sessions, three with parents and three with day care personnel, to identify key issues of concern for nutrition education of preschool to early primary age children and to receive reactions to message concepts relevant to food guidance for young children. The results of the focus group sessions along with additional information will be used by USDA to develop prototype nutrition education materials. During phase two of this study, pre-testing of the developed prototype materials with parents or day care personnel in settings most appropriate for their use will be conducted.

Affected Public: Parents and day care personnel of young children ages two to six years.

Estimated Number of Respondents: 72.

Estimated Time Per Response: 4 hours (focus group) and 2 hours (pre-testing).

Estimated Total Annual Burden on Respondents: 252 hours.

Dated: July 22, 1997.

William E. Ludwig,

Administrator, Food and Consumer Service.

[FR Doc. 97–19945 Filed 7–28–97; 8:45 am]

BILLING CODE 3410–30–M

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

City of Albany, Kentucky, Cagle Water Expansion Project; Final Environmental Impact Statement

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of availability of the Record of Decision for the City of Albany, KY, Cagle Water Expansion Project, Final Environmental Impact Statement.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS), pursuant to its responsibility as Lead Agency, and in conjunction with its cooperating agencies, the U. S. Department of Housing and Urban Development, and the U. S. Department of Commerce, Economic Development Administration is providing notice of the availability of the Record of Decision (ROD) for the Final Environmental Impact Statement (FEIS) prepared for the proposed water treatment plant expansion in the City of Albany, Kentucky. The EIS was prepared pursuant to the National Environmental Policy Act of 1969 (NEPA) (U.S.C. 4231 et seq.) in accordance with the Council on Environmental Quality (CEQ) regulations for implementing the procedural provisions of NEPA (40 CFR 1500–1508) and Agency regulations (7 CFR part 1940, subpart G).

The ROD was signed on July 24, 1997. RUS has decided to fund the City of Albany's proposal. The proposed action is to finance an expansion to an existing water treatment plant that will increase its treatment capacity from 2.0 million gallons per day (MGD) to 5.0 MGD. As a result of this action, RUS considered the potential environmental effects of potential businesses that would locate in and around the Clinton County, Kentucky area as a result of additional

supplies of potable water becoming available. As a result of this action, Cagle's, Inc. will likely build a poultry processing plant in Clinton County and support facilities, such as a feed mill, hatchery, poultry farms, and associated utility lines. The proposal is supported by and consistent with local initiatives developed by the Kentucky Highlands Empowerment Zone and the Clinton County Empowerment Zone Community, Incorporated.

ADDRESSES: Copies of the ROD are available on request from: Mark S. Plank, USDA, Rural Utilities Service, Engineering and Environmental Staff, 1400 Independence Avenue, SW, Mail Stop 1571, Washington, DC 20250, telephone (202) 720–1649, fax (202) 720–0820, or e-mail: mplank@rus.usda.gov.

A copy of the ROD can be obtained over the Internet at http://www.usda.gov/rus/water/ees/ees.htm.

Copies of the ROD will be available for public review during normal business hours at the following locations:

Clinton County Public Library, 205 Burkeville Road, Albany, KY 40601, (606) 387–5989.

Goodnight Memorial Library, 203 South Main, Franklin, KY 42134, (502) 586–8397.

Simpson County Extension Service, 300 N. Main Street, Franklin, KY 42134, (502) 586–4484.

Warren County Extension Service, 1117 Cabell Drive, Bowling Green, KY 42102–1018, (502) 842–1681.

Bowling Green Public Library, 1225 State Street, Bowling Green, KY 42102, (502) 843–1438.

Helm-Cravers Library, 1 Big Red Way, Western Kentucky University, Bowling Green, KY 42101, (502) 745–3951.

Dated: July 23, 1997.

Richard H. Mansfield,

Acting Deputy Administrator, Water and Environmental Program.

[FR Doc. 97–19860 Filed 7–28–97; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

AGENCY: Bureau of the Census.

Title: 1998 American Community Survey.

Form Number(s): ACS–1/1A, –10/10A, –12(L)/12A(L), –13(L)/13A(L), –14(L)/14A(L), –16(L)/16A(L), –20/20A, –30/30A.

Agency Approval Number: 0607–0810.

Type of Request: Revision of a currently approved collection.

Burden: 72,325 hours.

Number of Respondents: 258,000.

Avg Hours Per Response: 30 minutes.

Needs and Uses: The Census Bureau is developing a methodology known as ''Continuous Measurement'' which will produce socioeconomic data on a continual basis throughout the decade for small areas and small subpopulations. The American Community Survey (ACS), implemented in November 1995, is a continuing full-scale data collection effort designed to determine the feasibility of a continuous measurement system. The survey includes samples in specific sites as well as a national sample to test response rates and our ability to obtain telephone numbers for nonresponse households. The data collected in this survey will be within the general scope and nature of those inquiries covered in the decennial census every ten years.

In addition to the present 8 survey sites, we plan to add 2 new sites: Richland and Kershaw counties, South Carolina, including the city of Columbia; and Broward County, Florida.

The objectives of the 1998 test are to:

—Develop and test sampling and data collection procedures in a number of different data collection situations

—Develop and implement procedures to create a national list of group quarters, and integrate housing unit and group quarters data collection

—Produce estimates for consecutive years for the continuing survey sites

—Investigate the effects of conducting the ACS at the same time and place as a census

The ACS will be conducted at the same time and place (Richland & Kershaw Counties) as the 2000 Dress Rehearsal. This is being done for reasons stated above. We will ensure that no household receiving the ACS questionnaire will also get the long-form census questionnaire.

Affected Public: Individuals or households.

Frequency: Monthly.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C, Section 182.

OMB Desk Officer: Jerry Coffey, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Jerry Coffey, OMB Desk Officer, room 10201, New Executive Office Building, Washington, DC 20503.

Dated: July 23, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–19928 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–849]

Postponement of Final Determination; Antidumping Investigation of Certain Cut-to-Length Carbon Steel Plate From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of postponement of final determination of sales at less than fair value.

EFFECTIVE DATE: July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Greg Weber or Stephen Jacques, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–3793.

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Rounds Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are in reference to the regulations, codified at 19 CFR part 353, as they existed on April 1, 1996.

Postponement of Final Determination

On July 8, 1997, Anshan Iron and Steel Complex (AISCO), a producer of subject merchandise, Angang International Trade Corporation (Anshan International), a wholly-owned AISCO subsidiary in China with its own business licence to import and export

merchandise, and Sincerely Asia, Limited (SAL), a partially owned Hong Kong affiliate of AISCO involved in sales of subject merchandise to the United States (collectively, Anshan); Baoshan Iron & Steel Corporation (Bao), a producer of subject merchandise, Bao Steel Group International Trade Corporation (Bao Steel ITC), a wholly-owned subsidiary of Bao responsible for selling Bao material domestically and abroad and B.M. International, a partially-owned U.S. subsidiary involved in U.S. sales (collectively, Baoshan); Shanghai Pudong Iron & Steel (Group) Co. Ltd. (Shanghai Pudong); Wuhan Iron & Steel Company (Wuhan), a producer of subject merchandise, International Economic and Trading Corporation (IETC), a wholly owned subsidiary responsible for exporting WISCO merchandise and Cheerwu Trader Ltd. (Cheerwu), a partially-owned Hong Kong affiliate of Wuhan involved in sales of the subject merchandise (collectively WISCO) requested a thirty-day extension of the final determination.

Pursuant to section 735(a)(2) of the Act, on July 10, 1997, China Metallurgical Import & Export Liaoning Company (Liaoning), an exporter of subject merchandise, and Wuyang Iron and Steel Company (Wuyang), which produced the merchandise sold by Liaoning, requested that the Department postpone the final determination until 135 days after the date of publication of the preliminary determination.

Liaoning accounts for a significant proportion of exports of the subject merchandise. In addition, we are not aware of any compelling reasons for denying this request. As a result, we are granting Liaoning's request that the final determination in this investigation be postponed until 135 days after the publication of the preliminary determination. Therefore, the final determination will be due no later than October 24, 1997. Pursuant to section 733(d) of the Act, suspension of liquidation will be extended accordingly. *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Pasta from Italy,* 61 FR 30326, 30326 (June 14, 1996).

In accordance with 19 CFR 353.38, case briefs must be submitted to the Assistant Secretary for Import Administration no later than Friday, August 29, 1997, and rebuttal briefs, no later than Friday, September 5, 1997. A list of authorities used and a summary of the arguments made in the briefs should accompany these briefs. Such summary should be limited to five pages total, including footnotes. We will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments made in case or rebuttal briefs.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room 1870, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b) oral presentations will be limited to issues raised in the briefs.

This notice of postponement is published pursuant to section 735(a)(2)(A) of the Act.

Dated: July 22, 1997.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 97–19950 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–820]

Ferrosilicon From Brazil: Partial Termination of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration , Department of Commerce.

ACTION: Notice of Partial Termination of Antidumping Duty Administrative Review.

SUMMARY: On April 24, 1997, the Department of Commerce (the Department) initiated administrative reviews of the antidumping duty order on Ferrosilicon from Brazil for three manufacturers and producers of ferrosilicon from Brazil: Companhia Ferroligas Minas Gerais-Minasligas (''Minasligas''), Companhia Cia de Ferroligas da Bahia (''Ferbasa'') and, Companhia Brasileria Carbuerto de Calcio, (''CBCC''), covering the period March 1, 1996 through February 28, 1997. The Department of Commerce has decided to terminate the review for Minasligas.

EFFECTIVE DATE: July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Sal Tauhidi or Cameron Werker, AD/CVD Enforcement Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–4851 and (202) 482–3874, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 20, 1997, Minasligas, CBCC, and Ferbasa, manufacturers and exporters of merchandise subject to this order, requested that the Department conduct administrative reviews of the antidumping duty order on ferrosilicon from Brazil for the period March 1, 1996 through February 28, 1997.

On April 24, 1997, the Department published in the **Federal Register** (62 FR 19988) a notice of initiation of administrative review with respect to Minasligas, CBCC and Ferbasas for the period March 1, 1996 through February 28, 1997. On July 7, 1997, Minasligas requested that it be allowed to withdraw its request for a review and that the review be terminated.

The Department's regulations, at 19 CFR 353.22(a)(5)(1994), state that ''the Secretary may permit a party that requests a review under paragraph (a) of this section to withdraw the request not later than 90 days after the date of publication of notice of initiation of the requested review. In light of the fact that Minasligas submitted a timely request for termination of this review, we have decided it is reasonable to allow Minasligas to withdraw its request for review. Accordingly, the Department if terminating this review for Minasligas. See Certain Stainless Steel Butt-Weld Pipe Fittings from Taiwan, Termination of Antidumping Duty Administrative Review, 61 FR 40406, (August 2, 1996) and Steel Wire Rope from Japan; Partial Termination of Antidumping Duty Administrative Reviews, 56 FR 41118 (August 19, 1991).

This notice serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning disposition of proprietary information disclosed under APO in accordance with § 353.34(d) of the Department's regulations. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation. We will issue appraisement instructions directly to the U.S. Customs Service.

This notice is in accordance with § 353.22(a)(5) of the Department's regulations (19 CFR 353.22(a)(5)).

Dated: July 18, 1997.

Jeffrey P. Bialos,

Principal Deputy Assistant Secretary Import Administration.

[FR Doc. 97–19949 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

International Trade Commission

[A–570–506]

Porcelain-on-Steel Cooking Ware From the People's Republic of China; Extension of Time Limit for Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for antidumping duty administrative review.

SUMMARY: The Department of Commerce (the Department) is extending the time limit for preliminary results of the administrative review of the antidumping duty order on porcelain-on-steel cooking ware from the People's Republic of China (PRC) to no later than December 31, 1997. The review covers the period December 1, 1995 through November 30, 1996. This extension is made pursuant to the Tariff Act of 1930, as amended by the Uruguay Round Agreements Act (the Act).

EFFECTIVE DATE: July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Suzanne King or Lorenza Olivas, Office of CVD/AD Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202) 482–2786.

POSTPONEMENT: Under section 751(a)(3)(A) of the Act, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit of 365 days. The Department find that it is not practicable to complete the preliminary results of the 1996 administrative review of the antidumping duty order on porcelain-on-steel-cooking ware from the PRC within this time limit. *See* Memorandum to the Acting Assistant Secretary for Import Administration (public document, on file in the Central Records Unit, Room B–099 of the Main Commerce Building).

In accordance with section 751(a)(3)(A) of the Act, the Department will extend the time for completion of the preliminary results of this review from September 2, 1997 to no later than December 31, 1997.

Dated: July 18, 1997.

Jeffrey P. Bialos,

Principal Deputy Assistant Secretary for Import Administration.

[FR Doc. 97–19948 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

Minority Business Development Agency

Agency Information Collection Activities: Proposed Collection; Comment Request—Title: Application for Funding To Operate Technical Assistance Projects (SF 424 and Evaluation Criteria) SF 424

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites other Federal agencies and the general public to take this opportunity to comment on proposed or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before September 29, 1997.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Juanita Berry, Minority Business Development Agency (MBDA), Room 5084, Washington, D.C. 20230, or call (202) 482–0404.

SUPPLEMENTARY INFORMATION:

I. Abstract

The SF 424 Narrative constitutes the Minority Business Development Agency's (MBDA) application for grants/cooperative agreements under its technical assistance programs. The Agency needs this information to evaluate applicants' experience and resources against uniform program standards. This will assist MBDA in accomplishing its mission of fostering the development of minority businesses.

II. Method of Collection

Annual written solicitation of federal financial assistance award applications.

III. Data

OMB Number: 0640–0006.

Type of Review: Renewal/Reinstatement, without change, of a currently approved collection.

Burden: 14,400 hours.

Affected Public: Individuals, State or local governments, Federal agencies, and profit and non-profit institutions.

Estimated Number of Respondents: 180.

Estimated Time Per Response: 80 hours.

Estimated Total Annual Burden Hours: 14,400.

Estimated Total Annual Cost Per Respondent: $0—no capital expenditures are necessary to respond.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 23, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–19887 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–21–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. 960726208–7142–02]

Approval of Withdrawal of Thirty-Three Federal Information Processing Standards Publications

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce that the Secretary of

Commerce has approved the withdrawal of thirty-three Federal Information Processing Standards (FIPS) Publications.

On September 3, 1996, notice was published in the **Federal Register** (61 FR 46444–46445) proposing withdrawal of thirty-two Federal Information Processing Standards (FIPS) Publications. Thirty-one of the thirty-two FIPS proposed for withdrawal are being withdrawn by this notice.

In addition, FIPS 147, Group 3 Facsimile Apparatus for Document Transmission, and 174, Federal Building Telecommunications Wiring Standard, are withdrawn by this notice. These standards were proposed for revision in the **Federal Register** (61 FR 10986–10992 dated March 18, 1996, and 61 FR 15783–15785 dated April 9, 1996), but are being withdrawn instead.

These thirty-three FIPS are being withdrawn because they are obsolete, or have not been updated to adopt current voluntary industry standards. Federal agencies and departments are directed by the National Technology Transfer and Advancement Act of 1995, Public Law 104–113, to use technical standards that are developed in voluntary consensus standards bodies. Consequently, there no longer is a need for FIPS that duplicate voluntary industry standards.

The written comments submitted by interested parties and other material available to the Department relevant to these publications were reviewed by NIST. On the basis of this review, NIST recommended that the Secretary approve the withdrawal of the thirty-three FIPS Publications, and prepared a detailed justification document for the Secretary's review in support of that recommendation.

The detailed justification document which was presented to the Secretary is part of the public record and is available for inspection and copying in the Department's Central Reference and Records Inspection Facility, Room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC 20230.

This notice provides only the FIPS publication number, title, and the technical specifications number for each of the thirty-three FIPS Publications being withdrawn:

—FIPS 1–2, Code for Information Interchange, Its Representations, Subsets, and Extension (ANSI X3.4–1986/R1992, X3.32–1990, X3.41–1990)
—FIPS 11–3, Guideline: American National Dictionary for Information Systems (ANSI X3.172–1990 & X3.172A–1992)
—FIPS 16–1, Bit Sequencing of Code for Information Interchange in Serial-By-Bit Data Transmission (ANSI X3.15–1976/R1983&R1990)
—FIPS 17–1, Character Structure and Character Parity Sense for Serial-By-Bit Data Communication in the Code for Information Interchange (ANSI X3.16–1976/(1983 & R1990)
—FIPS 19–2, Catalog of Widely Used Code Sets
—FIPS 22–1, Synchronous Signaling Rates Between Data Terminal and Data Communication Equipment (ANSI X3.1–1976)
—FIPS 34, Guide for the Use of International System of Units (SI) in Federal Information Processing Standards Publications
—FIPS 49, Guideline on Computer Performance Management: An Introduction
—FIPS 57, Guidelines for the Measurement of Interactive Computer Service Response Time and Turnaround Time
—FIPS 58–1, Representations of Local Time of the Day for Information Interchange (ANSI X3.43–1986)
—FIPS 59, Representations of Universal Time, Local Time Differentials, and United States Time Zone References for Information Interchange (ANSI X3.51–1975)
—FIPS 68–2, BASIC (ANSI X3.113–1987)
—FIPS 70–1, Representation of Geographic Point Locations for Information Interchange (ANSI X3.61–1986)
—FIPS 75, Guideline on Constructing Benchmarks for ADP System Acquisitions
—FIPS 76, Guideline for Planning and Using a Data Dictionary System
—FIPS 77, Guideline for Planning and Management of Database Applications
—FIPS 86, Additional Controls for Use with American National Standard Code for Information Interchange (ANSI X3.64–1979/R1990)
—FIPS 88, Guideline on Integrity Assurance and Control in Database Administration
—FIPS 94, Guideline on Electrical Power for ADP Installations
—FIPS 96, Guideline for Developing and Implementing a Charging System for Data Processing Services
—FIPS 99, Guideline: A Framework for the Evaluation and Comparison of Software Development Tools
—FIPS 104–1, ANS Codes for the Representation of Names of Countries, Dependencies, and Areas of Special Sovereignty for Information Interchange
—FIPS 109, Pascal (ANSI/IEEE 770X3.97–1983/R1900)
—FIPS 110, Guideline for Choosing a Data Management Approach
—FIPS 123, Specification for a Data Descriptive File for Information Interchange (DDF) (ANSI/ISO 8211–1985/R1992)
—FIPS 124, Guideline on Functional Specifications for Database Management Systems
—FIPS 126, Database Language NDL (ANSI X3.133–1986)
—FIPS 147, Group 3 Facsimile Apparatus for Document Transmission
—FIPS 152, Standard Generalized Markup Language (SGML) (ISO 8879–1986)
—FIPS 156, Information Resource Dictionary System (IRDS) (ANSI X3.138–1988&X3.138A–1991)
—FIPS 157, Guideline for Quality Control of Image Scanners (ANSI/AIIM MS44–1998)
—FIPS 158–1, The User Interface Component of the Applications Portability Profile (MIT X Version 11, Release 5)
—FIPS 174, Federal Building Telecommunications Wiring Standard (ANSI/EIA/TIA–568–1991)

EFFECTIVE DATE: This withdrawal is effective July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Shirley Radack, National Institute of Standards and Technology, Gaithersburg, MD 20899, telephone (301) 975–2833.

Authority: Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology after approval by the Secretary of Commerce pursuant to Section 5131 of the Information Technology Management Reform Act of 1996 and the Computer Security Act of 1987, Pub. L. 104–106.

Dated: July 22, 1997.

Elaine Bunten-Mines,

Director, Program Office.

[FR Doc. 97–19839 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–CN–M

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Provisional Applications

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce (DoC), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the

Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before September 29, 1997.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert J. Spar, Patent and Trademark Office (PTO), Washington, DC 20231, telephone number (703)305–9285.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Uruguay Round Agreements Act, Public Law 103–465, mandates a 20-year patent term and provisional applications. The information in this collection is needed by the PTO to accurately identify and promptly and properly process provisional applications, as required by the Act.

II. Method of Collection

By mail, facsimile or hand carry when the applicant or agent files a patent application with the Patent and Trademark Office (PTO) or submits subsequent papers during the prosecution of the application to the PTO.

III. Data

OMB Number: 0651–0037.

Type of Review: Renewal without change.

Affected Public: Individuals or households, business or other non-profit, not-for-profit institutions and Federal Government.

Estimated Number of Respondents: 6,600.

Estimated Time Per Response: 8 hours.

Estimated Total Annual Respondent Burden Hours: 52,800 hours per year.

Estimated Total Annual Respondent Cost Burden: $1,584,000/year—no capital costs will need to be expended by respondents.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: July 23, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–19888 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Statutory Invention Registration

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce (DoC), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before September 29, 1997.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert J. Spar, Patent and Trademark Office (PTO), Washington, DC 20231, telephone number (703) 305–9285.

SUPPLEMENTARY INFORMATION:

I. Abstract

A patent applicant may request to have the application published as a statutory invention registration. This collection includes information needed by the PTO to review and approve/deny such requests.

II. Method of Collection

By mail, facsimile or hand carry when the applicant or agent files a patent application with the Patent and Trademark Office (PTO) or submits subsequent papers during the prosecution of the application to the PTO.

III. Data

OMB Number: 0651–0036.

Type of Review: Renewal without change.

Affected Public: Individuals or households, business or other non-profit, not-for-profit institutions and Federal Government.

Estimated Number of Respondents: 113.

Estimated Time Per Response: 0.4 hour.

Estimated Total Annual Respondent Burden Hours: 45 hours per year.

Estimated Total Annual Respondent Cost Burden: $7,910 per year—no capital costs must be incurred by respondents to provide the information.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: July 23, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–19889 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Secrecy/License to Export

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce (DoC), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before September 29, 1997.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert J. Spar, Patent and Trademark Office (PTO), Washington, DC 20231, telephone number (703) 305–9285.

SUPPLEMENTARY INFORMATION:

I. Abstract

In the interest of national security, patent laws and rules place certain limitations on the disclosure of information contained in patents and patent applications and on the filing of applications for patent in foreign countries. The Patent and Trademark Office (PTO) collects information to determine whether the patent laws and rules have been complied with, and to grant licenses to file abroad when appropriate.

II. Method of Collection

By mail, facsimile or hand carry when the applicant or agent files a patent application with the Patent and Trademark Office (PTO) or submits subsequent papers during the prosecution of the application to the PTO.

III. Data

OMB Number: 0651–0034.

Type of Review: Renewal without change.

Affected Public: Individuals or households, business or other non-profit, not-for-profit institutions and Federal Government.

Estimated Number of Respondents: 2,156.

Estimated Time Per Response: 0.5 hour.

Estimated Total Annual Respondent Burden Hours: 1,078.

Estimated Total Annual Respondent Cost Burden: $188,650—no capital expenses will need to be expended to provide information.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; Subcommittee (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: July 23, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–19890 Filed 7–28–97; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton and Wool Textile Products Produced or Manufactured in Colombia

July 23, 1997.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202 927–5850). For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); the Uruguay Round Agreements Act.

The current limit for category 443 is being increased for shift and carryover, decreasing the limit for category 315 to account for the shift.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 61 FR 66263, published on December 17, 1996). Also see 61 FR 58038, published on November 12, 1996.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOUs, the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

July 23, 1997.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 4, 1996, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, and man-made fiber textiles and textile products, produced or manufactured in Colombia and exported during the twelve-month period which began on January 1, 1997 and extends through December 31, 1997.

Effective on July 29, 1997, you are directed to adjust the limits for the following categories, as provided for by the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing (ATC):

Category	Adjusted twelve-month limit [1]
315	21,602,483 square meters.
443	148,446 numbers.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1996.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 97–19953 Filed 7-28-97; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

Office of the Secretary

Civilian Health and Medical Program of the Uniform Services (CHAMPUS); Defense and Veterans Head Injury Program (DVHIP) Demonstration Project

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: This notice is to advise parties of a demonstration project where the DoD will participate in the Defense and Veterans Head Injury Program (DVHIP) Protocol II *Traumatic Brain Injury (TBI) Rehabilitation: A Controlled, Randomized Multicenter Study of Two Interdisciplinary Programs with Adjuvant Pharmacotheraphy.* Under the demonstration, DoD will participate in a controlled trail of cognitive therapy for TBI at four participating Department of Veterans Affairs medical facilities. Participation in these clinical trails will provide access to cognitive rehabilitation for TRICARE/CHAMPUS beneficiaries when their conditions meet the study protocol edibility criteria. DoD financing of these procedures will assist in meeting clinical trail goals and arrival at conclusions regarding the safety and efficacy of cognitive rehabilitation in the treatment of TBI. This demonstration project is under the authority of Title 10, United States Code (U.S.C.), Chapter 55, Section 1092.

EFFECTIVE DATE: August 1, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Tariq Shahid, Health Care Program Development Branch, Office of Civilian Health and Medical Program of the Uniform Services (OCHAMPUS), Aurora, CO, 80045–6900, telephone (303) 361–1401 or Ms. Ann Fazzini, Health Care Policy Analyst, Program Development Branch, OCHAMPUS, Aurora, CO 80045–6900, telephone (303) 361–1403.

SUPPLEMENTARY INFORMATION:

A. Background

TBI is the principal cause of death and disability for young Americans, at an estimated cost of over $39 billion per year. Important advances have been made in prevention and acute care, yet the costs of TBI rehabilitation have been growing exponentially. This is in spite of the fact that few, if any, TBI rehabilitation modalities have been subjected to the degree of scientific scrunity for efficacy and cost efficiency that is usually applied to other medical treatments. The escalating economic burden that TBI places on individual families, as well as on society, is unlikely to be controlled until this issue is resolved.

The Conference Report on the Defense Appropriations Act for Fiscal Year 1992 (House Report 102–328) supported the Department of Defense (DoD) to start an initiative for DoD victims of head injuries. The DVHIP was established in February 1992, and funded in part direct appropriations to DoD (Health Affairs) from Congress. The DVHIP represents a unique collaboration among the DoD, Department of Veterans Affairs (DVA), and the Brain Injury Association. DVHIP objectives ensure that all DVA eligible TBI patients receive TBI-specific evaluation and follow-up, while at the same time collecting standardized patient outcome data that will allow the DVHIP to compare the relative efficacy and cost of various TBI treatment and rehabilitations strategies, and to help define optimal care for victims of TBI.

There are four DVA facilities participating in the DVHIP study. These are located in Palo Alto, California; Minneapolis, Minnesota; Richmond, Virginia; and, Tampa, Florida. The DVHIP can currently provide services at its DVA facilities only for those patients who are eligible for care within the DVA system. At present this excludes a significant number of TRICARE/CHAMPUS patients from participation in the DVHIP.

Cognitive rehabilitation is a generic term lacking a standard definition. The term is used to describe varied systems of multidisciplinary services intended to remedy related cognitive, daily living and psychosocial ability impairments which are secondary to organic brain damage.

The current state of the medical literature does not allow for a TRICARE/CHAMPUS benefit for cognitive rehabilitation in the treatment of TBI patients. The DVHIP is conducting a randomized, prospective trail that would hasten the answers to the current questions of the contribution(s), if any, of cognitive rehabilitation. The study will address the efficacy of cognitive rehabilitation versus traditional rehabilitation of beneficiaries with TBI (moderate to severe closed head injury) in prospective randomized clinical trials of 364 patients. In addition, patients randomized into either the cognitive or the traditional rehabilitation program will be further randomized to receive pharmacotherapy or placebo. The pharmacotherapy will consist of methylphenidate if the patient is determined to be non-depressed and apathetic, and sertraline for all others.

Because CHAMPUS relies upon outcome-based medical literature in the formulation of its coverage policy regarding cognitive rehabilitation, the DoD should assist with research protocols that will directly contribute to the body of science regarding cognitive rehabilitation. DoD financing of these procedures will assist in meeting clinical trial goals and arrival at conclusions regarding the safety and efficacy of cognitive rehabilitation in the treatment of TBI.

B. TRICARE/CHAMPUS Experience

TRICARE/CHAMPUS cost shares TBI rehabilitative services such as speech therapy, physical therapy and occupational therapy. However, cognitive rehabilitation therapy, which is frequently provided as a component of TBI care, is considered investigational under TRICARE/CHAMPUS.

TRICARE/CHAMPUS, by regulation, does not approve payment for experimental or investigational procedures. Any change in the experimental status of cognitive rehabilitation in the treatment of TBI logically awaits the findings from well controlled studies of clinically meaningful endpoints such as the DVHIP Demonstration Project.

Among TRICARE/CHAMPUS beneficiaries of all ages (5.4 million) approximately 5,000 have head injuries each year with 1,300–1,400 requiring hospitalization.

Overall CHAMPUS billed charges for 1,360 TBI admissions in Fiscal Year (FY) 1992 were approximately $31.1 million (or $1,908 per day), and the total allowed amount (i.e., the government payments and beneficiary cost shares) was almost $21.4 million (or $1,309 per day). This included acute and rehabilitation hospitalizations and skilled nursing home costs.

CHAMPUS billed charges for 78 admissions in FY 1992 for services in rehabilitation hospitals were approximately $5.8 million (or $1,343 per day), and the total allowed amount was $5.46 million (or $1,247 per day). This represented about 4,378 rehabilitation hospital bed days.

CHAMPUS billed charges for 31 admissions in FY 1992 for services in skilled nursing homes were approximately $2.2 million (or $930 per day), and the total allowed amount was approximately $2.15 million (or $902 per day). This represented about 2387 skilled nursing home bed days.

Together, the total CHAMPUS cost for services in rehabilitation hospitals and in skilled nursing homes for beneficiaries with TBI in FY 1992 was

approximately $7.6 million for 109 admission requiring 6,765 bed days. The average length of stay was 62 days with an average per diem of $1,125 in FY 1992. Based on increases in the Consumer Price Index (Urban) for medical care, the average per diem for 1996 under CHAMPUS is estimated to be $1,320. This contrasts with a current estimated average cost of about $600 per day in participating VAMCs.

C. Caseload, Costs

The design of the rehabilitation protocol is limited to patients between the ages of 17–55 years. CHAMPUS population projections for fiscal year (FY) 1996 included approximately 2.1 million beneficiaries between 17 and 55 years of age.

This Demonstration Project is conservatively projected to provide inpatient rehabilitation services for approximately 100 TRICARE/CHAMPUS patients with TBI each year.

The Demonstration Project involves the costs for the inpatient bed days required for the initial evaluation, rehabilitation and subsequent re-evaluations at the participating DVA facilities. The beneficiary cost-shares applicable under TRICARE/CHAMPUS shall apply under the Demonstration Project.

On average, each TRICARE/CHAMPUS beneficiary participating in the clinical trials would require about three bed days for evaluation for the protocol, sixty bed days for the rehabilitation services, and five bed days each for the post-discharge evaluation and three follow-on re-evaluations. Over the entire Demonstration Project each participant would require about eighty-three bed days.

The current annual CHAMPUS costs for 100 admissions in rehabilitation hospitals and skilled nursing facilities for the beneficiaries with TBI are estimated to be $8.18 million. This contrasts with the estimated cost of $4.38 million for 100 admissions during the first year of the demonstration. This represents a projected cost avoidance of approximately $3.8 million to DoD during the first year of the demonstration while providing access to rehabilitation services for the beneficiaries.

D. Operation of the Demonstration

The Demonstration is projected to last for three years. The Assistant Secretary of Defense (Health Affairs) will designate a Project Officer in the Office of the Deputy Assistant Secretary of Defense (DASD) for Clinical Services. The DASD (Clinical Services) provides oversight for the DVHIP operations.

Office of CHAMPUS will provide for demonstration claim processing via specific contractual arrangement with a claims processor. The contractor would not be involved in clinical issues but will direct patients to the nearest participating DVA facility for evaluation.

Dated: July 21, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–19829 Filed 7–28–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Privacy and Security on Publicly Accessible DoD Internet Services

AGENCY: Department of Defense, Office of the Secretary of Defense (Public Affairs).

ACTION: Notice.

SUMMARY: This is a voluntary notice by the Department of Defense to inform those who use publicly accessible defense information on the Internet what measures are being taken to gather information about visits and to protect the integrity of Department of Defense Internet systems. Effective immediately, the DoD changing its notice to users to notify them of what we are doing and why.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Silva, OASD(PA), Room 2E791, 1400 Defense Pentagon, Washington, DC 20301–1400 or on-line via the DefenseLINK message form at http://www.dtic.mil/defenselink/faq/comment.html.

SUPPLEMENTARY INFORMATION: In its ongoing efforts to provide open, honest and accurate information to the public, the Department is hereby notifying those who use publicly accessible defense information on the Internet what measures are being taken to gather information about visits and to protect the integrity of Department of Defense Internet systems and why it is necessary to do so.

First, most World Wide Web services record information about web site visits for site management purposes. DoD uses industry-standard software to gather basic data about web site visits. This data is used for site management purposes, such as assessing what information is of most and least interest to users, determining technical design specifications, and identifying system performance or problem areas.

Second, computer vandalism has become an ever increasing problem over the past few years. These attacks can lead to the alteration of information that is used and trusted by millions of people. It is becoming more and more important for the Department to take a more proactive role in protecting its computer systems from these attacks. Therefore, to insure that the DoD public web services remain available to all users and to protect them from fraudulent, unlawful or abusive use, the Department is employing industry-standard methods to monitor network traffic to identify unauthorized attempts to upload or change information, or otherwise cause damage.

No other attempts are made to identify individual users or their usage habits. Raw data logs are used for no other purposes and are scheduled for regular destruction in accordance with National Archives and Records Administration General Schedule 20.

Third, the Department is publishing the attached ''privacy and security notice'' on its publicly accessible Internet systems to inform users what we are doing and why.

DefenseLINK (http://www.dtic.mil/defenselink/) is the official World-Wide Web Information Service from the Department of Defense and is the starting point for locating U.S. defense information around the world. The purpose of DefenseLINK is to provide the public with a single, unified starting point for information about the Department of Defense, its organization and its functions. DefenseLINK provides direct access to the Information Services established by each military service. These Defense World Wide Web services contain many Defense publications, answers to frequently asked questions about the department, news releases and photographs. Information within these public access services may be distributed or copied. Use of appropriate byline/photo/image credits is requested.

Below is the new privacy and security notice being implemented on all DoD publicly accessible Internet systems.

Link from Index.html pages—''*Please read this privacy and security notice.*''

( )—indicates sections to be tailored at the installation level.

[ ]—indicates hyperlinks.

*—indicates information located at the hyperlink destination indicated.

Privacy and Security Notice

1. (DefenseLINK) is provided as a public service by the ([Office of the Assistant Secretary of Defense-Public

Affairs] and the [Defense Technical Information Center]).

2. Information presented on (DefenseLINK) is considered public information and may be distributed or copied. Use of appropriate byline/photo/image credits is requested.

3. For site management, [information is collected] * for statistical purposes. This government computer system uses industry-standard software to create summary statistics, which are used for such things as assessing what information is of most and least interest, determining technical design specifications, and identifying system performance or problem areas.

4. For site security purposes and to ensure that this service remains available to all users, this government computer system employs industry-standard methods to monitor network traffic to identify unauthorized attempts to upload or change information, or otherwise cause damage.

5. No other attempts are made to identify individual users or their usage habits. Raw data logs are used for no other purposes and are scheduled for regular destruction in accordance with [National Archives and Records Administration General schedule 20].

6. Unauthorized attempts to upload information or change information on this service are strictly prohibited and may be punishable under the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.

7. If you have any questions or comments about the information presented here, please forward them to (us using the DefenseLINK [Comment Form]).

Example: Information Collected From DefenseLINK for Statistical Purposes

Below is an example of the information collected based on a standard request for a World Wide Web document:

pm2e–1–678.afbdsop.com—[28/Jan/1997:00:00:01–0500]
''GET/defenselink/news/nr012797.html HTTP/1.0'' 200 16704
Mozilla 3.0

pm2e–1–678.afbdsop.com—this is the domain and IP address of the requester (you as the visitor). In this case, (....com) the requester is coming from a commercial address instead of a military or educational institution address.

[28/Jan/1997:00:00:01–0500]—this is the date and time of the request

''GET/defenselink/news/nr012797.html HTTP/1.0''—this is the location of the requested file on DefenseLINK

200—this is the status code—200 is OK—the request was filled

16704—this is the size of the requested file in bytes

Mozilla 3.0—this identifies the type of browser software used to access the page, which indicates what design parameters to use in constructing the pages.

Requests for other types of documents use similar information. No other user-identifying information is collected.

Dated: July 22, 1997.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–19828 Filed 7–28–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

National Defense Panel Meeting

AGENCY: DoD, National Defense Panel.

ACTION: Notice.

SUMMARY: This notice sets forth the schedule and summary agenda for the meeting of the National Defense Panel on August 7, 1997. In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law No. 92–463, as amended (5 U.S.C. App. II, (1982)), it has been determined that this National Defense Panel meeting concerns matters listed in 5 U.S.C. 552b(c)(1)(1982), and that accordingly this meeting will be closed to the public from 0830–1700, August 7, 1997 in order for the Panel to discuss classified material.

DATES: August 7, 1997.

ADDRESSES: Suite 532, 1931 Jefferson Davis Hwy., Arlington, VA.

SUPPLEMENTARY INFORMATION: The National Defense Panel was established on January 14, 1997 in accordance with the Military Force Structure Review Act of 1996, Public Law 104–201. The mission of the National Defense Panel is to provide the Secretary of Defense and Congress with an independent, non-partisan assessment of the Secretary's Quadrennial Defense Review and an Alternative Force Structure Analysis. This analysis will explore innovative ways to meet the national security challenges of the twenty-first century.

Proposed Schedule and Agenda

The National Defense Panel will meet in closed session from 0830–1700 on August 7, 1997. During the closed session on August 7 the Panel will be meeting at the Crystal Mall 3 office to receive briefings on developing alternative military strategies for achieving American national security objectives in the year 2020—Strategy Option Development Task Plan, and determining existing and future potential solutions to capability requirements and assess those candidate solutions relative to feasibility/performance, cost, risk and other appropriate measures of merit-Capabilities Assessment Work Plan.

The determination to close the meeting is based on the consideration that it is expected that discussion will involve classified matters of national security concern throughout.

FOR FURTHER INFORMATION CONTACT: Please contact the National Defense Panel at (703) 602–4176/6.

Dated: July 22, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–19830 Filed 7–28–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Department of the Air Force

Record of Decision for the Disposal and Reuse of Rickenbacker Air National Guard Base (ANGB), Ohio

On May 15, 1997, the Air Force issued the Revised Supplemental Record of Decision (RSROD) for the Disposal and Reuse of Rickenbacker (ANGB). The decisions included in this RSROD have been made in consideration of, but not limited to, the information contained in the Final Environmental Impact Statement (FEIS) for the Disposal and Reuse of Rickenbacker ANGB, which was filed with the United States Environmental Protection Agency (US EPA) and made available to the public on February 17, 1995.

Rickenbacker ANGB realigned on September 30, 1994, pursuant to the Defense Authorization Amendments and Base Closure and Realignment Act (DBCRA), of 1990 (10 United States Code 2687) and recommendations of the Defense Base Closure and Realignment Commission. Rickenbacker ANGB was recommended for closure by the 1991 Commission, but as a result of a proposal by the State of Ohio, the 1993 Commission recommended that Rickenbacker ANGB be realigned rather than closed, so that Ohio Air National Guard units could continue to operate in a cantonment area within the base.

* Link from above—''information is collected''

The purpose of the FEIS was to analyze and disclose the potential environmental consequences of the disposal of real property and the reuse of the base outside the area retained by the US Air Force.

The Air Force issued a Record of Decision (ROD) on May 19, 1995, which documented a series of decisions in regard to parcel disposal, the organizations or agencies to receive certain parcels; the means for parcel disposal (Federal transfer, public benefit conveyance, negotiated sale, or public sale); and the mitigation measures to be adopted. The Air Force issued a Supplemental Record of Decision (SROD) on April 23, 1996, which clarified that the base electrical system would be disposed of by negotiated sale. The SROD also, made modifications to the ROD concerning the size of various parcels of land to be transferred to the Army and the Rickenbacker Port Authority (RPA).

Since the SROD was issued, the RPA and other Federal agencies have requested that the SROD and ROD be revised to reconcile certain property disposal decisions. Consequently, this RSROD adjusted the acreage of various parcels of land and clarified the intended disposal of the water and waste water sewer system to the RPA.

These disposal activities and any associated mitigation measures will proceed with minimal adverse impact to the environment. This action conforms with applicable Federal, State and local statutes and regulations, and all reasonable and practical efforts have been incorporated to minimize harm to the local public and the environment.

Any questions regarding this matter should be directed to Mr. John P. Carr, Program Manager at (703) 696–5547. Correspondence should be sent to: AFBCA/DA, 1700 North Moore Street, Suite 2300, Arlington, VA 22209–2802.

Barbara A. Carmichael,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 97–19934 Filed 7–28–97; 8:45 am]

BILLING CODE 3910–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Deadline for Submission of Donation Application for the Aircraft Carrier Ex-MIDWAY (CV 41)

SUMMARY: The Department of the Navy hereby gives notice of the deadline of November 12, 1997 for submission of a donation application for the Multi-Purpose Aircraft Carrier ex-MIDWAY (CV 41), located at the Naval Inactive Ship Maintenance Facility, Bremerton, Washington, under the authority of 10 U.S.C. Section 7306. Eligible recipients include: (1) Any State, Commonwealth, or possession of the United States or any municipal corporation or political subdivision thereof; (2) the District of Columbia; or (3) any not-for-profit or nonprofit entity. Transfer of a vessel under this law shall be made at no cost to the United States Government. The transferee will be required to maintain the vessel in a condition satisfactory to the Secretary of the Navy as a static museum/memorial. Prospective transferees must submit a comprehensive, detailed application addressing their plans for managing the significant financial, technical, and environmental responsibilities that accompany ships donated under this program.

FOR FURTHER INFORMATION CONTACT: Ms. Gloria Carvalho, Congressional and Public Affairs Office, Naval Sea Systems Command, NAVSEA 00D1C, 2531 Jefferson Davis Hwy, Arlington, VA 22242–5160, telephone number (703) 602–1575.

Dated: July 18, 1997.

M.D. Sutton,

LCDR, JAGC, USN, Federal Register Liason Officer.

[FR Doc. 97–19844 Filed 7–28–97; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Exclusive License; M.E. Harris & Company

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to M.E. Harris & Company a revocable, nonassignable, exclusive license in the United States to practice the Government owned inventions described in: U.S. Patent Number 5,190,624 entitled Electrorheological Fluid Chemical Processing; U.S. Patent Number 5,194,181 entitled Process for Shaping Articles from Electrosetting Compositions; U.S. Patent Number 5,518,664 entitled Programmable Electroset Processes; U.S. Patent Pending; Navy Case Number 75,833 entitled Programmable Electroset Materials and Process.

Anyone wishing to object to the grant of this license has 60 days from the date of this notice to file written objections along with supporting evidence, if any. Written objections are to be filed with the Naval Surface Warfare Center, Carderock Division, Code 004, 9500 MacArthur Blvd., West Bethesda, MD 20817–5700.

FOR FURTHER INFORMATION CONTACT: Mr. Dick Bloomquist, Director, Technology Transfer, Naval Surface Warfare Center, Carderock Division, Code 0117, 9500 MacArthur Blvd., West Bethesda, MD 20817–5700, telephone number (301) 227–4299.

Dated: July 16, 1997.

M. D. Sutton,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 97–19832 Filed 7–28–97; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Arbitration Panel Decision Under the Randolph-Sheppard Act

AGENCY: Department of Education.

ACTION: Notice of arbitration panel decision under the Randolph-Sheppard Act.

SUMMARY: Notice is hereby given that on June 11, 1996, an arbitration panel rendered a decision in the matter of *Mississippi Department of Rehabilitation Services* v. *United States Department of Defense, Department of the Air Force (Docket No. R–S/94–3).* This panel was convened by the U.S. Department of Education pursuant to 20 U.S.C. 107d–1(b), upon receipt of a complaint filed by the Mississippi Department of Rehabilitation Services.

FOR FURTHER INFORMATION CONTACT: A copy of the full text of the arbitration panel decision may be obtained from George F. Arsnow, U.S. Department of Education, 600 Independence Avenue, SW., Room 3230, Mary E. Switzer Building, Washington, DC 20202–2738. Telephone: (202) 205–9317. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–8298.

SUPPLEMENTARY INFORMATION: Pursuant to the Randolph-Sheppard Act (20 U.S.C. 107d–2(c)), the Secretary publishes in the **Federal Register** a synopsis of arbitration panel decisions affecting the administration of vending facilities on Federal and other property.

Background

On or about June 24, 1993, the U. S. Department of Defense, Department of the Air Force (Air Force), issued a request for proposals (RFP) for full food services at Keesler Air Force Base, Mississippi. The Mississippi Department of Rehabilitation Services, State licensing agency (SLA), responded

to the RFP, providing both technical and cost information.

In August 1993, the Air Force's Technical Evaluation Committee (TEC) met to evaluate the SLA's proposal along with the other proposals that were submitted. Subsequently, the Air Force contracting officer informed the SLA that its proposal was determined to be within the competitive range along with 15 of the original 19 offerors. On September 16, 1993, the TEC sent a discussion letter to the SLA and to the other offerors who were within the competitive range. Shortly thereafter, the SLA responded to the Air Force regarding the questions asked in the discussion letter.

On September 28, 1993, the SLA filed a protest with the Air Force's contracting officer concerning the Air Force's alleged failure to award the SLA the food service contract following the determination that it was within the competitive range. The SLA contends that, based upon Department of Defense (DOD) Directive 1125.3 and regulations of the Secretary of Education (34 CFR 395.33(b)), either the contract must be awarded to the SLA following a determination that the SLA is within the competitive range established by the contracting office or the contracting office must consult with the Secretary of Education regarding its justification for not doing so. The Air Force never responded to the SLA's protest, nor was the contract awarded to the SLA.

On November 12, 1993, the TEC met to review the offerors' responses to questions asked regarding DOD's concerns and determined that 9 of the 13 remaining offerors' proposals, including the SLA's, were acceptable. Subsequently, the contracting officer sent a second round of discussion letters to all 13 offerors, including those that were deemed technically unacceptable. The SLA received the second discussion letter on November 23, 1993, and again responded, objecting to the Air Force's failure to comply with Randolph-Sheppard requirements. At the same time, in order to maintain its eligibility for the award, the SLA fully responded to all discussion questions.

The TEC again met and conducted a final technical evaluation, at which time the SLA's proposal was determined to be fully acceptable from a technical standpoint. However, the contracting officer later made a determination that the SLA's proposal was technically unacceptable as the result of its response to a section of the RFP regarding the use of sighted employees.

Subsequently, a second competitive range was established by the Air Force's contracting officer. Following the establishment of the second competitive range, the SLA received from the Air Force a Determination for Exclusion letter indicating the exclusion of the SLA's proposal. The Air Force's stated reasons for the exclusion of the SLA's proposal from the second competitive range were the SLA's response on the use of sighted employees at the facility and the SLA's higher pricing structure compared to the other offerors within the competitive range.

Arbitration Panel Decision

The issues heard by the arbitration panel were—(1) Whether the Air Force violated the Randolph-Sheppard Act, 20 U.S.C. 107 *et seq.*; Air Force regulation 34–2, DOD Directive 1125.3; Section L–901 of RFP No. F222600–92–R–0156; and Randolph-Sheppard regulations in 34 CFR 395.33 by its alleged failure to award the full food service contract to the SLA and by its alleged failure to consult with the Secretary of Education following the determination that the SLA was within the competitive range; and (2) Whether the Air Force's alleged arbitrary, capricious, and bad faith conduct violated the Administrative Procedures Act, 5 U.S.C. 706, and Federal Acquisition Regulations, 48 CFR 1.602–2(b) and 48 CFR 15.608(a).

As to the first issue, the panel majority concluded that the process by which the Air Force determined the competitive range in March 1994 was fully in accord with all governing laws and regulations. Specifically, the majority members concluded that an earlier decision by the contracting officer that 4 of the 19 offerors had submitted noncomplying proposals, based upon a review for technical sufficiency, did not establish a competitive range within the meaning of DOD Directive 1125.3 or Randolph-Sheppard regulations in 34 CFR 395.33(b). The panel majority ruled that the Air Force determined a competitive range, as contemplated under the governing regulations, only after full cost data was submitted by the 15 remaining offerors, including the SLA, who were solicited on the basis of their technically sufficient initial submissions. The panel majority concluded the SLA was properly excluded from the final competitive range because its proposal was not competitive in comparison to the numerous proposals offering lower costs.

One panel member dissented regarding this part of the majority opinion.

The panel members unanimously ruled that the Air Force violated the Randolph-Sheppard Act and applicable regulations by excluding the SLA from the competitive range, in part, because of its alleged failure to give the assurance required concerning minimizing the employment of sighted persons at the cafeteria facility. The panel ruled that compliance issues raised by this requirement should be addressed through pre-contract negotiations with the contractor and not by exclusion from the bid process. The majority of the panel ruled, however, that this action by the Air Force was a harmless error inasmuch as the SLA's proposal had been properly excluded on other grounds.

The views and opinions expressed by the panel do not necessarily represent the views and opinions of the U.S. Department of Education.

Dated: July 23, 1997.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 97–19865 Filed 7–28–97; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Arbitration Panel Decision Under the Randolph-Sheppard Act

AGENCY: Department of Education.

ACTION: Notice of arbitration panel decision under the Randolph-Sheppard Act.

SUMMARY: Notice is hereby given that on April 4, 1997, an arbitration panel rendered a decision in the matter of *Robert Smith* v. *Michigan Commission for the Blind (Docket No. R–S/96–4).* This panel was convened by the U.S. Department of Education pursuant to 20 U.S.C. 107d–1(a), upon receipt of a complaint filed by petitioner, Robert Smith.

FOR FURTHER INFORMATION CONTACT: A copy of the full text of the arbitration panel decision may be obtained from George F. Arsnow, U.S. Department of Education, 600 Independence Avenue, SW., Room 3230, Mary E. Switzer Building, Washington, DC 20202–2738. Telephone: (202) 205–9317. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–8298.

SUPPLEMENTARY INFORMATION: Pursuant to the Randolph-Sheppard Act (20 U.S.C. 107d–2(c)), the Secretary publishes in the **Federal Register** a synopsis of each arbitration panel decision affecting the administration of vending facilities on Federal and other property.

Background

This dispute arose as the result of the revocation of Mr. Robert Smith's vending license by the Michigan Commission for the Blind, the State licensing agency (SLA). The SLA alleged that Mr. Smith failed to comply with several vending facility program rules governing the operation and administration of the Michigan Business Enterprise Program.

Mr. Smith had operated facilities in the SLA's vending facility program since May, 1987. His most recent assignment was the Mason Building Cafeteria, which he operated from September 1993 until his license revocation, which was effective June 16, 1995.

The SLA alleged that Mr. Smith failed to—(1) Furnish reports in a proper manner; (2) pay set-aside fees in a timely fashion by the required due date; (3) operate the facility in accordance with applicable health laws and rules; (4) cooperate with commission representatives in the performance of official duties and responsibilities; and (5) pay food suppliers in a timely manner in accordance with applicable credit policies.

On June 23, 1995, Mr. Smith filed a request with the SLA for a full evidentiary hearing stating that he had complied with all applicable rules and regulations concerning the Mason Building Cafeteria. A State fair hearing was held on January 4, 1996.

On January 19, 1996, an Administrative Law Judge (ALJ) recommended that, based on the hearing testimony, Mr. Smith's license not be revoked and that the SLA continue to assist him with respect to the deficiencies relating to the management and operation of the Mason Building Cafeteria.

By letter dated March 6, 1996, Mr. Smith was informed that the Michigan Commission for the Blind Board of Directors on February 19, 1996, rejected the recommendation of the ALJ that complainant's license not be revoked. This decision constituted final agency action.

Mr. Smith sought review of this decision by a Federal arbitration panel. A hearing on this case was held on August 1, 1996.

Arbitration Panel Decision

The issues before the arbitration panel were—(1) Whether the SLA's action in revoking Mr. Smith's license to operate the Mason Building Cafeteria was in accordance with the Randolph-Sheppard Act (the Act), implementing regulations, and State rules and regulations; and (2) whether the SLA engaged in undue harassment and caused injury to the complainant by his license revocation and the closing of the cafeteria.

A majority of the panel ruled that Mr. Smith was in violation of the Act, implementing regulations, and State rules and regulations by reason of his failure to furnish reports as required and to pay set-aside fees. In addition, the majority of the panel found that Mr. Smith did not operate the facility in accordance with health laws and rules. Not only was he in violation of the laws administered by the county health department, but he failed to meet the health and safety standards of the SLA. Mr. Smith also failed to follow specific instructions concerning sanitation and disposal of waste products and to pay for merchandise in accordance with the terms of credit of his suppliers.

Further, the majority of the arbitration panel stated that the allegation of harassment had been carefully examined and found to be without merit. There had been no showing through testimony or evidence that Mr. Smith was treated disparately or that the rules were applied to him in an arbitrary or capricious manner.

The majority of the panel concluded that the SLA's action in revoking Mr. Smith's license was in accordance with the Act, the implementing regulations, and State rules and regulations and that Mr. Smith was not subjected to undue harassment in the operation of his facility.

One panel member dissented.

The views and opinions expressed by the panel do not necessarily represent the views and opinions of the U.S. Department of Education.

Dated: July 23, 1997.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 97–19866 Filed 7–28–97; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 97–36–NG]

Office of Fossil Energy; Coastal Gas Marketing Company; Order Granting Long-Term Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Coastal Gas Marketing Company (CGM) long-term authorization to import up to 5 MMcf of natural gas of Canadian natural gas for a period of ten years, beginning on November 1, 1997, under the terms and conditions of a letter agreement dated February 20, 1997, with Ranger Oil Limited. This natural gas may be imported at Niagara Falls, New York, or at alternative border points with transportation facilities accessible by CGM.

This order is available for inspection and copying in the Office of Natural Gas & Petroleum Import and Export Activities docket room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C., July 7, 1997.

Wayne E. Peters,

Manager, Natural Gas Regulation, Office of Natural Gas and Petroleum Import and Export Activities, Office of Fossil Energy.

[FR Doc. 97–19918 Filed 7–28–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 97–41–NG]

Office of Fossil Energy; Coenergy Trading Company; Order Granting Long-Term Authorization To Export Natural Gas To Canada For Subsequent Re-Import To The United States

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued DOE/FE Order No. 1280 on June 20, 1997, granting CoEnergy Trading Company a ten-year authorization to export up to 80,000 Mcf per day (29.2 Bcf annually) to Canada for re-import to the United States. The term of the authorization is for a period commencing November 1, 1998, through October 31, 2008. This gas may be exported from the United States at the existing interconnection of TransCanada PipeLines Limited and Great Lakes Gas Transmission Limited Partnership near St. Clair, Michigan, and re-imported into the United States at the interconnection of the Trans Quebec and Maritimes Pipeline and the proposed Portland Natural Gas Transmission System near Pittsburg, New Hampshire.

This order is available for inspection and copying in the Office of Natural Gas & Petroleum Import and Export

Activities Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585–0350, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C., June 11, 1997.

Wayne E. Peters,

Manager, Natural Gas Regulation, Office of Natural Gas and Petroleum Import and Export Activities, Office of Fossil Energy.

[FR Doc. 97–19919 Filed 7–28–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Pacific Northwest Coordination Agreement (PNCA)

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of Availability of Record of Decision (ROD).

SUMMARY: The Administrator and Chief Executive Officer (CEO) of BPA, acting for BPA, and, as Chairman of the United States Entity (the Administrator of BPA and the Division Engineer, North Pacific Division of the United States Army Corps of Engineers (Corps)), acting on behalf of the United States Entity, has decided that the 1964 Pacific Northwest Coordination Agreement (PNCA) should be revised and retained.

To facilitate the implementation of the 1997 PNCA, BPA, the Regional Director of the Pacific Northwest Regional Office of the Bureau of Reclamation (Reclamation), and the Division Engineer of the Northwestern Division (formerly the North Pacific Division) of the United States Army Corps of Engineers (Corps) have decided to clarify each agency's role and responsibility under the 1997 PNCA in a Memorandum of Agreement.

This decision is consistent with the Columbia River System Operation Review (SOR) Final Environmental Impact Statement (EIS) (DOE/EIS–0170, November 1995) which evaluated the potential impacts of five alternatives for regional coordination.

ADDRESSES: Copies of the SOR Final EIS, Appendix R of the EIS (which presents the environmental review for the PNCA), and complete copies of this ROD are available from BPA's Communications Office, P.O. Box 12999, Portland, Oregon 97212. Copies of the documents may also be obtained by calling BPA's toll-free document request line at: 1–800–622–4520.

FOR FURTHER INFORMATION CONTACT: Mr. Phil Mesa—PGPL–DITT2, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon, 97208–3621, phone number (360) 418–2152.

SUPPLEMENTARY INFORMATION: The current PNCA was executed in 1964 as an important component of regional plans to maximize the Northwest's hydro resource capability. Maximization also included the development of three storage projects on the Columbia River in Canada pursuant to the terms of the 1964 Columbia River Treaty between Canada and the United States (Treaty). These storage dams provide regulated streamflows that enable Federal and non-Federal hydroelectric projects downstream in the United States to produce additional power benefits. The Treaty requires the United States to deliver to Canada one-half of these downstream power benefits (known as the Canadian Entitlement). The non-Federal utilities of the region committed to provide a portion of the share of Treaty benefits required to be delivered to Canada. In return, the United States Government agreed to participate in coordinated operation. The Federal and non-Federal allocation was the subject of a separate ROD; the Canadian Entitlement Allocation Extension Agreement (CEAEA) ROD was issued on April 29, 1997.

The 1964 PNCA expires in 2003. The region's obligation to return Columbia River Treaty benefits continues, at a minimum, until 2024. The 1997 PNCA, which revises the 1964 PNCA, extends through 2024.

Issued in Portland, Oregon, on July 18, 1997.

Randall W. Hardy,

Administrator and CEO, Bonneville Power Administration, and Chairman, United States Entity.

[FR Doc. 97–19921 Filed 7–28–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Energy Information Administration, DOE.

ACTION: Agency information collection activities: Proposed collection; comment request.

SUMMARY: The Energy Information Administration (EIA) is soliciting comments concerning the proposed modifications and extensions of the following Electric Power Forms:

EIA–411, ''Coordinated Bulk Power Supply Program Report,''
EIA–412, ''Annual Report of Public Electric Utilities,''
NN–417R, ''Electric Power Systems Emergency Report,''
EIA–759, ''Monthly Power Plant Report,''
EIA–826, ''Monthly Electric Utility Sales and Revenue Report with State Distributions,''
EIA–860, ''Annual Electric Generator Report,''
EIA–861, ''Annual Electric Utility Report,''
EIA–867, ''Annual Nonutility Power Producer Report,'' and
EIA–900, ''Monthly Nonutility Sales for Resale Report.''

EIA is also requesting comments on a proposed new Form EIA–417A, ''Annual Summary of Emergency Occurrences.''

DATES: Written comments must be submitted on or before September 29, 1997. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the DOE contact listed below of your intention to do so as soon as possible.

ADDRESSES: Send comments to John G. Colligan, Energy Information Administration, Coal and Electric Data and Renewables Division, EI–524, U.S. Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585–0650; telephone (202) 426–1174; e-mail jcolliga@eia.doe.gov; and FAX (202) 426–1311.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of forms and instruction sets should be directed to John Colligan at the address listed above.

SUPPLEMENTARY INFORMATION:

I. Background
II. Current Actions
III. Request for Comments

I. Background

In order to fulfill its responsibilities under the Federal Energy Administration Act of 1974 (Pub. L. 93–275) and the Department of Energy Organization Act (Pub. L. 95–91), the EIA is obliged to carry out a central, comprehensive, and unified energy data and information program. As part of this program, EIA collects, evaluates, assembles, analyzes, and disseminates data and information related to energy resource reserves, production, demand,

and technology, and related economic and statistical information relevant to the adequacy of energy resources to meet demands in the near and longer term future for the Nation's economic and social needs.

The EIA, as part of its continuing effort to reduce paperwork and respondent burden (required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13)), conducts a presurvey consultation program to provide the general public and other Federal agencies with an opportunity to comment on proposed and/or continuing reporting forms. This program helps to ensure that requested data can be provided in the desired format, reporting burden is minimized, reporting forms are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Also, EIA will later seek approval by the Office of Management and Budget (OMB) for the collections under Section 3507(h) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, Title 44, U.S.C. Chapter 35).

II. Current Actions

The EIA requests (a) a 3-year extension, through December 31, 2000, for all forms listed, and (b) modifications as well as time extension(s) to the specific forms as described below. The proposed changes the EIA is requesting through this action reflect the current state of the electric power industry. Additional changes may be required, prior to the new expiration date, in order to be up-to-date with the rapidly changing industry.

Form EIA–411, ''Coordinated Bulk Power Supply Program,'' no change.

Form EIA–412, ''Annual Report of Public Electric Utilities,'' no change.

Form EIA–417A, ''Annual Summary of Emergency Occurrences,'' a new form will be added to the EIA electric power survey program. This collection will request statistical data on the type, duration, impact, and nature of electric emergency occurrences and power outages. The data will be reported annually by all entities operating/owning any portion of the integrated electrical system, and Alaska, Hawaii, and the trust territories. A simple check-off system technique of reporting will be available to respondents who (1) experienced no incidents and (2) were not impacted by external occurrences during the year.

Form NN–417R, ''Electric Power Systems Emergency Report.'' The form number and name will be changed to the EIA–417R, ''Electric Power Systems Emergency Report.'' The survey frame and reporting schedule will remain unchanged.

EIA–759, ''Monthly Power Plant Report,'' no change.

Form EIA–826, ''Monthly Electric Utility Sales and Revenue Report with State Distributions.'' The form name will be changed to ''Monthly Electric Industry Sales and Revenue Report with State Distributions,'' to more accurately define the survey respondent frame. This will permit reporting of sales and revenues by electric utilities and power marketers. The collection of these data is required as the retail marketing of electric power is growing under the restructuring of the electric power industry.

EIA–860, ''Annual Electric Generator Report,'' no change.

Form EIA–861, ''Annual Electric Utility Report.'' The form and instructions will be modified as delineated below.

(a) Change the form name to ''Annual Electric Energy Industry Report,'' to more clearly identify the respondent population consisting of electric utilities and power marketers which constitutes the frame of this survey.

(b) Expand reporting to include generation (in megawatthours) in (1) the existing service territory and (2) in the marketing territory as well.

(c) Reduce the number of Demand-Side Management (DSM) questions, (Schedule V), to 1 page (eliminated 2 pages), and thereby reduce respondent reporting requirements and burden. The need for DSM data are diminishing as restructuring/unbundling throughout the industry takes place.

(d) Request more explicit identification of electric industry participants. Parent and subsidiary company relationships are essential as new and different types of electric energy entities come into being during the restructuring.

(e) Add questions regarding completed mergers and acquisitions. This is necessary to maintain the respondent universe control and to accurately purge the respondent list of organizations no longer having reporting responsibilities.

(f) Request reporting of service territories by State and County, once every three years. These data are needed to establish and maintain an accurate baseline of existing and expanding distribution systems.

(g) Request respondents with sales for resale under full power requirement contracts to record the highest firm required demand, and for full requirement, whose power is supplied by others under long term contract are asked to identify the ending dates of the contract. The data will be used to analyze changes affecting reliability.

(h) Add questions to report sales for resale, and end use sales by NERC region.

Form EIA–867, ''Annual Nonutility Power Producer Report.'' The form and instructions will be modified to convert Standard Industrial Classification (SIC) codes to the North American Industry Classification System (NAICS) codes, the international standard of industrial classification. This conversion is necessary to sustain coherence and standardization of industry identification for both domestic and foreign sales and transfers of electric generation.

Form EIA–900, ''Monthly Nonutility Sales for Resale Report.'' The form and instructions will be modified to: (a) Add a question to collect monthly gross generation. (b) Add a question to collect monthly sales to other end users.

III. Request for Comments

Prospective respondents and other interested parties should comment on the actions discussed in item II. The following guidelines are provided to assist in the preparation of responses. Please indicate to which form(s) your comments apply.

General Issues

A. Are the proposed collections of information necessary for the proper performance of the functions of the agency? Does the information have practical utility? Practical utility is defined as the actual usefulness of information to or for an agency, taking into account its accuracy, adequacy, reliability, timeliness, and the agency's ability to process the information it collects.

B. What enhancements can EIA make to the quality, utility, and clarity of the information to be collected?

As a Potential Respondent

A. Are the instructions and definitions clear and sufficient? If not, which instructions require clarification?

B. Can data be submitted by the due date?

C. Public reporting burden estimates for each form collection are shown below. Burden includes the total time, effort, or financial resources expended to generate, maintain, retain, or disclose or provide the information.

EIA–411, ''Coordinated Bulk Power Supply Program Report,''—20.77 hrs. per response (no change from previous estimate).

EIA–412, ''Annual Report of Public Electric Utilities,''—30.3 hrs. per

response (no change from previous estimate).

EIA–417R, ''Electric Power Systems Emergency Report and Annual Summary of Emergency Occurrences,''—2.89 hrs. per response (no change from previous estimate). (Note: The frequency, magnitude, and duration of emergency occurrences are hard to predict, therefore making reporting times hard to predict.)

EIA–417A, ''Annual Summary of Emergency Occurrences,''—3.0 hrs. per response (new form).

EIA–759, ''Monthly Power Plant Report,''—1.4 hrs. per response (no change from previous estimate).

EIA–826, ''Monthly Electric Utility Sales and Revenue Report with State Distributions,''—1.4 hrs. per response (previous estimate was 1.3 hrs.).

EIA–860, ''Annual Electric Generator Report,''—15.3 hrs. per response (no change from previous estimate).

EIA–861, ''Annual Electric Energy Industry Report,''—7.9 hrs per response (previous estimate was 6.85 hrs.).

EIA–867, ''Annual Nonutility Power Producer Report,''—2.12 hrs. per response (no change from previous estimate).

EIA–900, ''Monthly Nonutility Sales for Resale Report,''—.30 hrs. per response (previous estimate was .25 hrs.).

Please comment on (1) the accuracy of our estimates and (2) how the agency could minimize the burden of the collections of information, including the use of automated collection techniques or other forms of information technology.

D. EIA estimates that respondents will incur no additional costs for reporting other than the hours required to complete the collections. What is the estimated: (1) total dollar amount annualized for capital and start-up costs, and (2) recurring annual costs of operating and maintaining and purchasing service costs associated with these data collections?

E. Do you know of any other Federal, State, or local agency that collects similar data? If you do, specify the agency, the data element(s), and the methods of collection.

As a Potential User

A. Can you use data at the levels of detail indicated on the forms?

B. For what purpose would you use the data? Be specific.

C. Are there alternate sources of data and do you use them? If so, what is their deficiencies and/or strengths?

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the form. They also will become a matter of public record.

Statutory Authority: Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13).

Issued in Washington, D.C. July 23, 1997.

Jay H. Casselberry,

Agency Clearance Officer, Statistics and Methods Group, Energy Information Administration.

[FR Doc. 97–19922 Filed 7–28–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2758–000]

Advantage Energy, Inc.; Notice of Issuance of Order

July 23, 1997.

Advantage Energy, Inc. (Advantage Energy) submitted for filing a rate schedule under which Advantage Energy will engage in wholesale electric power and energy transactions as a marketer. Advantage Energy also requested waiver of various Commission regulations. In particular, Advantage Energy that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Advantage Energy.

On July 14, 1997, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Advantage Energy should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Advantage Energy is authorized to issue securities and assume obligations or liabilities as a guarantor, endorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Advantage Energy's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protest, as set forth above, is August 13, 1997. Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E. Washington, D.C. 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19874 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–627–000]

Alabama-Tennessee Natural Gas Company; Notice of Request Under Blanket Authorization

July 23, 1997.

Take notice that on July 10, 1997, Alabama-Tennessee Natural Gas Company (Alabama-Tennessee), P.O. Box 3869, Muscle Schoals, Alabama 35662–3869, filed in Docket No. CP97–627–000 a request pursuant to Section 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to construct and operate a delivery point in Morgan County, Alabama, for the delivery of natural gas to Worthington Steel of Decatur, LLC. (Worthington), under Alabama-Tennessee's blanket certificate issued in Docket No. CP85–359–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Alabama-Tennessee states that the estimated volumes to be delivered to Worthington are 4,000 MMBtu on a peak day and 1,460,000 MMBtu on an annual basis.

Alabama-Tennessee states further that the estimated cost to install the delivery point would be $117,000.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a

protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19868 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2792–000]

Community Electric Power Corporation; Notice of Issuance of Order

July 23, 1997.

Community Electric Power Corporation (CEPC) submitted for filing a rate schedule under which CEPC will engage in wholesale requested waiver of various Commission regulations. In particular, CEPC requested that the Commission grant blanket approval under 18 CFF Part 34 of all future issuances of securities and assumptions of liability by CEPC.

On July 15, 1997, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by CEPC should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, CEPC is authorized to issue securities and assume obligations or liabilities as a guarantor, endorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of CEPC's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 14, 1997. Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E. Washington, D.C. 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19873 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT97–55–000]

Distrigas of Massachusetts Corporation; Notice of Refund Report

July 23, 1997.

Take notice that on July 15, 1997, Distrigas of Massachusetts Corporation (DOMAC) tendered for filing a Refund Report in compliance with the Commission's Order dated February 22, 1995, in Gas Research Institute (GRI), Docket No. RP95–124–000.

DOMAC states that it received a wire transfer of $13,791 from GRI on May 30, 1997, representing overcollection of the 1996 GRI Tier 1 funding. DOMAC further states that it will not be crediting this refund to its customers on a pro rata basis because it has no customers who are eligible for such credits.

Any person desiring to be heard or protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests shall be filed on or before July 30, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashall,

Secretary.

[FR Doc. 97–19876 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–142–005]

K N Interstate Gas Transmission Co.; Notice of Tariff Filing

July 23, 1997.

Take notice that on June 18, 1997 K N Interstate Gas Transmission Co. (KNI) tendered for filing as part of its FERC Gas Tariff, the following revised tariff sheets, to be effective August 1, 1997:

Third Revised Volume No. 1–B
Original Sheet No. 89A
First Revised Volume No. 1–D
Original Sheet No. 71A

KNI states that these tariff sheets are being filed to comply with the Commission's order in Docket No. RP97–142–003, issued July 3, 1997, directing KNI to submit actual tariff sheets related to Order No. 587–C.

KNI states that copies of the filing were served upon KNI's jurisdictional customers, interested public bodies, and all parties to the proceedings.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. All protests filed with the Commissions will be considered by it in determining the appropriate action to be taken, but will not serve to make the Protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19877 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP96–809–003]

Maritimes & Northeast Pipeline, L.L.C.; Notice of Amendment to Application

July 23, 1997.

Take notice that on July 11, 1997, Maritimes & Northeast Pipeline, L.L.C. (Maritimes), a Delaware limited liability company, filed an amendment to its September 23, 1996, application for a certificate of public convenience and necessity, under to Section 7(c) of the Natural Gas Act, and Part 157 of the Commission's regulations. Maritimes's September 23rd application seeks authority to construct, own, operate and maintain a natural gas pipeline from Wells, Maine to the U.S.-Canadian border near Woodland, Maine and related pipeline laterals and compressor stations. The July 11th amendment changes certain parts of the route of Maritimes's proposed pipeline, changes certain parts of the lateral routes, and relocates the proposed Richmond Compressor Station. The details of the route changes are more fully set forth in the amendment which is on file and available to the public for inspection.

Maritimes's September 23 Application is for Phase II of its Project, as previously revised by its amendment filed on February 24, 1997 in Docket No. CP96–809–002. Maritimes's Phase II Project involves the construction of natural gas pipeline facilities from Wells to Woodland, as well as the provision of natural gas transportation service through those facilities. The overall Maritimes Project is part of a natural gas transportation facility for the Sable Offshore Energy Project (SOEP), which is being developed by a consortium of United States and Canadian energy companies. The SOEP is scheduled to bring offshore natural gas to the Maritimes Provinces in Canada and the northeastern United States in 1999. The joint construction, ownership and operation of a part of the Phase II facilities, from Wells to Westbrook, Maine is pending in Docket No. CP97–238–000; Portland Natural Gas Transmission System (PNGTS) is the joint applicant, along with Maritimes. The February 24th amendment reflects changes in Phase II of Maritimes's project related to the joint facilities.

The July 11th Amendment reflects the reroutes of the proposed mainline and lateral facilities and the relocation of a compressor station that have been adopted by Maritimes since its filing of the original pipeline rout in the September 23rd Application. Maritimes states that the reroutes and compressor station location reflected in the Amendment will result in:

(i) a reduction in the number of major water body crossings;

(ii) a reduction in the number of miles of wetlands crossed;

(iii) a reduction in impacts to residences; and,

(iv) an increase in the number of miles of proposed pipeline that are located adjacent to or within existing rights-of-way.

Maritimes provided the following summary description of the three largest mainline reroutes that it has adopted as part of its Phase II primary route, as well as a description of the new compressor station location and the Northern Alternative in the Richmond and Kennebec River area. Smaller route modifications are described in the exhibits and resource reports which accompanied the amendment.

The Bangor Hydro reroute, located in Washington and Hancock Counties, Maine, comprises about 46 miles of the reroutes proposed in the July 11th Amendment. Maritimes incorporated this reroute into its primary route to follow the existing Stud Mill Road corridor, the proposed Bangor Hydro corridor, and existing landowner-owned roads. Maritimes says that these landowner-owned roads provide both an existing corridor for the pipeline and potential overlap for work space where none originally existed. Maritimes says that although the Bangor Hydro reroute results in an increase of over three miles to the length of the original route, it determined that the environmental benefits of this reroute (mitigating the impact to existing forested lands and existing salmon habitat and deer yards in the Machias and Narraquagus River watersheds) warranted incorporated this reroute into its primary route.

Maritimes has incorporated another reroute in the Bangor-Brewer area, known as the Bangor Water District (BWD) Reroute. This reroute comprises about 20 miles long. Maritimes proposes to reroute the pipeline in this area since its original route traversed portions of a BWD watershed that comprises one of the sources of potable water for the Bangor-Brewer area, and to avoid Camp Roosevelt, a property owned by the Katahdin Council (Boy Scouts of America).

Maritimes has also proposed 12 miles of reroute in the Richmond, Maine area. Maritimes says that the Richmond Reroute is the result of its effort to improve its original route by avoiding residential and wetlands areas and by mitigating the environmental impacts and engineering constraints related to crossing existing roadways and the Kennebec Rivers. As a result of this reroute, Maritimes proposes to relocate its proposed compressor station in the Richmond area, which was originally proposed to be located near Milepost 145, to a location near revised Milepost 143. The environmental report provided by Maritimes as part of the July 11th amendment discusses a ''Northern Alternative Route'' which Maritimes says would make greater use of existing rights-of-way in the Richmond area.

Maritimes does not expect the reroutes and the change in compressor station location applied for in the Amendment to materially affect the cost of the Phase II Project, although the revised Exhibit G shows a 4.2-mile net increase in the length of the proposed mainline. The July 11th Amendment does not reflect any changes in Maritimes's proposed Phase II cost estimate, rates or tariff or related exhibits.

Maritimes requests a preliminary determination on non-environmental issues in this proceeding by September 1997. With respect to a final certificate addressing environmental issues, Maritimes requests that the Commission act upon its amended application as soon as reasonably possible.

Any person desiring to be heard or to make any protest with reference to said Amendment should on or before August 13, 1997, file with the Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's rules. Any person who has already filed a motion to intervene in Docket Nos. CP96–809–000 or CP96–809–002 need not file again to obtain intervenor status.

Take further notice that pursuant to the authority contained in and subject to the jurisdiction conferred upon the Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this Amendment if no petition to intervene is filed within the time required herein or if the

Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is filed or if the Commission, on its own motion, believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Maritimes & Northeast to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19867 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–648–000]

Natural Gas Pipeline Company of America; Notice of Request Under Blanket Authorization

July 23, 1997.

Take notice that on July 17, 1997, Natural Gas Pipeline Company of America (Applicant), 701 East 22nd Street, Lombard, Illinois 60148, filed in Docket No. CP97–648–000 a request pursuant to Sections 157.205, 157.216, and 157.212 of the Commission's Regulations under the Natural Gas Act for authorization to abandon a 1.8 mile segment of Applicant's 36-inch Howard Street Lateral located in Cook County, Illinois, by sale to The Peoples Gas Light and Coke Company (PGLC), a local distribution company; to abandon by removal certain meter facilities comprising Applicant's existing Rogers Park delivery point, the point where Applicant currently delivers gas to PGLC; and to construct and operate a replacement delivery point to PGLC on the Howard Street Lateral, under blanket certificate issued in Docket No. CP82–402–000,[1] all as more fully set forth in the request for authorization on file with the Commission and open for public inspection.

Applicant states that the proposed activity is to create a direct interconnection between the systems of PGLC and Northern Illinois Gas Company (NI–Gas), without constructing substantial new facilities, and while maintaining Applicant's delivery capabilities to both systems off the Howard Street Lateral. Applicant has agreed to sell and PGLC has agreed to purchase the 1.8 miles of pipe for the sum of $225,000. Applicant states that this facility has a net book value of $0, and the $225,000 price is based on the approximate value of the right-of-way. PGLC's purchase of the facility will make it unnecessary for PGLC to acquire new right-of-way for the construction of a new facility to accomplish the PGLC/NI-Gas interconnect.

Applicant states that all transportation volumes being delivered at the current Rogers Park delivery point would be reassigned to the replacement delivery point, which would retain the Rogers Park name and have comparable delivery capability. There is no contemplated change between the present and proposed quantities of gas to be delivered; nor, will there be an impact on Applicant's peak day and annual deliveries as a result of the change in delivery point location. Applicant states that its customers on the subject facilities have no objection to the proposal.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is failed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19870 Filed 7–28–96; 8:45 am]

BILLING CODE 6717–01–M

[1] *See*, 20 FERC § 62,415 (1982).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–646–000]

NorAm Gas Transmission Company; Notice of Request Under Blanket Authorization

July 23, 1997.

Take Notice that on July 17, 1997, NorAm Gas Transmission Company (NGT), 1600 Smith Street, Houston, Texas 77002, filed in Docket No. CP97–646–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to construct and operate a tap in Arkansas under NGT's blanket certificate issued in Docket No. CP82–348–000 and CP82–384–001 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

NGT proposes to install and operate a 1-inch tap and a first cut regulator on its Line JM–19 in Lee County, Arkansas. The total estimated volumes to be delivered to these facilities are 2,600 MMBtu annually and 16 MMBtu on a peak day. The estimated total cost of the project is $2,743.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19869 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–654–000]

NorAm Gas Transmission Company; Notice of Request Under Blanket Authorization

July 23, 1997.

Take notice that on July 18, 1997, NorAm Gas Transmission Company (NGT), 1600 Smith Street, Houston, Texas 77002, filed in Docket No. CP97–654–000 a request pursuant to Sections 157.205, 157.211, and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211, and 157.216) for authorization to abandon certain facilities in Arkansas and construct and operate certain facilities in Arkansas to deliver gas to Tyson Foods, Inc. under NGT's blanket

certificate issued in Docket No. CP82–384–000 and CP82–384–001 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

NGT specifically seeks authority to replace and upgrade a delivery tap. Specifically, NGT seeks authority to abandon an existing 6-inch meter and two 1-inch regulators and install a 6-inch electronic turbine meter and two, 1-inch regulators in Logan county, Arkansas. No services will be abandoned. NGT's total cost are estimated at $8,942.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19871 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–3187–000]

Power Systems Group, Inc.; Notice of Issuance of Order

July 23, 1997.

Power Systems Group, Inc. (Power Group) submitted for filing a rate schedule under which Power Group will engage in wholesale electric power and energy transactions as a marketer. Power Group also requested waiver of various Commission regulations. In particular, Power Group requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Power Group.

On July 11, 1997, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Power Group should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Power Group is authorized to issue securities and assume obligations or liabilities as a guarantor, endorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Power Group's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 11, 1997. Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E. Washington, D.C. 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19875 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL97–43–000]

QST Energy Trading, Inc. v. Central Illinois Public Service Company and Union Electric Company; Notice of Filing

July 23, 1997.

Take notice that on June 25, 1997, pursuant to Section 306 of the Federal Power Act, 16 U.S.C. § 825e, and Rule 206 of the Rules of Practice and Procedure of the Federal Energy Regulatory Commission (Commission), 18 CFR 385.206, QST Energy Trading, Inc. (QST) tendered for filing a Verified Complaint, Request for Interim Relief and Request for Shortened Answer Period against Central Illinois Public Service Company (CIPS) and Union Electric Company (UE). QST alleges that CIPS and UE, which is operating CIPS' transmission system, have refused to provide QST with monthly firm transmission service to deliver firm energy and capacity which is being sold by CIPS. This Complaint concerns a series of acts which are alleged to be anti-competitive: CIPS' refusal to provide QST with firm transmission service after CIPS agreed to make a firm power sale; CIPS' and UE's refusal to provide transmission service which MAIN indicated was available; the refusal by CIPS and UE to provide a copy of the study done which is allegedly the basis for refusing to provide transmission service; and UE's anticompetitive use of CIPS' transmission system to deny available service.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before August 8, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not service to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this application are on file with the Commission and are available for public inspection. Answers to the complaint shall be due on or before August 8, 1997.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19872 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–224–007]

Sea Robin Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

July 23, 1997.

Take notice that on July 18, 1997, Sea Robin Pipeline Company (Sea Robin) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following revised tariff sheets in compliance with the Commission's Order No. 587 and the Commission's

July 3, 1997 Order in this docket, to become effective June 1, 1997:

Second Substitute Fifth Revised Sheet No. 7
First Substitute First Revised Sheet No. 22

On July 17, 1996, the Commission issued Order No. 587 in Docket No. RM96–01–000 which revised the Commission's regulations governing interstate natural gas pipelines to require such pipelines to follow certain standardized business practices issued by the Gas Industry Standards Board (GISB) and adopted by the Commission in said Order. 18 C.F.R. 284.10(b).

On July 3, 1997, the Commission issued an order in this docket in response to Sea Robin's June 4, 1997, filing to comply with Order No. 587. The order required Sea Robin to revise and submit a compliance filing to be effective June 1, 1997. Sea Robin was directed to include in its Tariff a statement clarifying application of the GISB established timelines for non-standard predetermined allocation (PDA) methodologies.

Sea Robin states that it has added a new Section 2.4(g) to its General Terms and Conditions to clarify that the GISB timelines will be applicable to any non-standard PDA methodologies. The Commission also directed Sea Robin to include on its rate sheet the volumetric capacity release rate based on an annual rate period and the 100% load factor derivation of its firm reservation rate. The Commission also ordered Sea Robin to eliminate the footnote containing the text of GISB Standard 5.3.22, which contains the methodology for calculating the volumetric capacity release rate on the rate sheet.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR Section 385.211). All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19880 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP97–137–000, RP97–182–000, RP97–224–000, RP97–138–000, RP97–310–000]

Southern Natural Gas Company, South Georgia Natural Gas Company, Sea Robin Pipeline Company, Shell Gas Pipeline Company, Garden Banks Gas Pipeline Company, LLC; Notice of Meeting

July 23, 1997.

Take notice that a meeting with Staff will be convened in the above-docketed proceedings on Thursday, July 31, 1997, at 1:00 p.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, D.C., 20426. The purpose of the meeting is to discuss the status of the new SoNet project and any impacts of a later implementation date. Any interested parties may attend.

For additional information, please contact Keith Pierce, 202–208–0525, or Leonard Burton, 202–208–1074, at the Commission.

Kevin P. Madden,

Director, Office of Pipeline Regulation.

[FR Doc. 97–19908 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–143–004]

TCP Gathering Co.; Notice of Tariff Filing

July 23, 1997.

Take notice that on July 1, 1997 TCP Gathering Co. (TCP) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following revised tariff sheet, to be effective August 1, 1997:

Second Revised Sheet No. 103

TCP states that this tariff sheet is being filed to comply with the Commission's letter order in Docket No. RP97–143–002, issued June 10, 1997.

TCP states that copies of the filing were served upon TCP's jurisdictional customers, interested public bodies, and all parties to the proceedings.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19878 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–143–005]

TCP Gathering Co.; Notice of Tariff Filing

July 23, 1997.

Take notice that on July 18, 1997 TCP Gathering Co. (TCP) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following revised tariff sheet, to be effective August 1, 1997:

Substitute Second Revised Sheet No. 103

TCP states that this sheet is being filed to adopt, in the August 1, 1997 effective sheet, the changes recently approved in the Commission's July 2, 1997 letter order in Docket No. RP97–143–003 incorporating certain Order No. 587 GISB standards to be effective June 1, 1997.

TCP states that copies of the filing were served upon TCP's jurisdictional customers, interested public bodies, and all parties to the proceedings.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. All protests filed with the Commissions will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19879 Filed 7–28–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting

July 23, 1997.

The following notice of meeting is published pursuant to section 3(A) of the Government in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C. 552B:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: July 30, 1997, 10 a.m.

PLACE: Room 2C, 888 First Street, N.E., Washington, D.C. 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda; * Note—Items Listed on the Agenda May Be Deleted Without Further Notice.

CONTACT PERSON FOR MORE INFORMATION: Lois D. Cashell, Secretary, Telephone (202) 208–0400. For a recording listing items stricken from or added to the meeting, call (202) 208–1627.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the reference and information center.

Consent Agenda—Hydro 680th Meeting—July 30, 1997, Regular Meeting (10 a.m.)

CAH–1.
DOCKET# P–2555, 005, KENNEBEC WATER DISTRICT
OTHER#S P–2556, 010, CENTRAL MAINE POWER COMPANY
P–2557, 007, CENTRAL MAINE POWER COMPANY
P–2559, 008, CENTRAL MAINE POWER COMPANY
UL96–7, 002, KENNEBEC WATER DISTRICT
UL96–8, 002, CENTRAL MAINE POWER COMPANY
UL96–9, 002, CENTRAL MAINE POWER COMPANY
UL96–10, 002, CENTRAL MAINE POWER COMPANY
CAH–2.
DOCKET# P–2984, 027, S.D. WARREN COMPANY
CAH–3.
OMITTED
CAH–4.
DOCKET# P–5, 029, THE MONTANA POWER COMPANY AND CONFEDERATED SALISH AND KOOTENAI TRIBES OF THE FLATHEAD RESERVATION
CAH–5.
DOCKET# P–2496, 012, EUGENE WATER & ELECTRIC BOARD
CAH–6.
DOCKET# P–6879, 018, SOUTHEASTERN HYDRO-POWER, INC.

Consent Agenda—Electric

CAE–1.
DOCKET# ER97–3271, 000, COMMONWEALTH EDISON COMPANY
CAE–2.
DOCKET# ER97–3221, 000, CONSUMERS ENERGY COMPANY
CAE–3.
DOCKET# ER97–3127, 000, MONTAUP ELECTRIC COMPANY
OTHER#S ER97–2800, 000, MONTAUP ELECTRIC COMPANY
CAE–4.
DOCKET# ER97–2340, 000, BOSTON EDISON COMPANY
CAE–5.
DOCKET# ER97–2810, 000, ENTERGY SERVICES, INC
CAE–6.
DOCKET# EF96–2011, 001, UNITED STATES DEPARTMENT OF ENERGY—BONNEVILLE POWER ADMINISTRATION
OTHER#S EF96–2021, 001, UNITED STATES DEPARTMENT OF ENERGY—BONNEVILLE POWER ADMINISTRATION
CAE–7.
DOCKET# TX97–6, 000, IDAHO POWER COMPANY
CAE–8.
DOCKET# EL94–13, 000, ENTERGY SERVICES, INC. AND GULF STATES UTILITIES COMPANY
CAE–9.
DOCKET# OA96–154, 000, CENTRAL ILLINOIS PUBLIC SERVICE COMPANY
CAE–10.
DOCKET# OA96–206, 000, EMPIRE DISTRICT ELECTRIC COMPANY
CAE–11.
OMITTED
CAE–12.
DOCKET# ER96–2741, 001, ARIZONA PUBLIC SERVICE COMPANY
CAE–13.
DOCKET# ER97–1932, 001, COMPETITIVE UTILILTY SERVICES CORPORATION
CAE–14.
DOCKET# EL96–28, 000, PACIFIC GAS AND ELECTRIC COMPANY
CAE–15.
DOCKET# EL96–2, 000, ASHBURNHAM MUNICIPAL LIGHT DEPARTMENT, ET AL. V. MAINE YANKEE ATOMIC POWER COMPANY
OTHER#S EL96–2, 001, ASHBURNHAM MUNICIPAL LIGHT DEPARTMENT, ET AL. V. MAINE YANKEE ATOMIC POWER COMPANY
CAE–16.
DOCKET# EL96–62, 000, ROCHESTER GAS AND ELECTRIC CORPORATION V. NIAGARA MOHAWK POWER CORPORATION
CAE–17.
OMITTED
CAE–18.
DOCKET# NJ96–1, 001, SOUTH CAROLINA PUBLIC SERVICE AUTHORITY
CAE–19.
DOCKET# NJ97–3, 000, UNITED STATES DEPARTMENT OF ENERGY—BONNEVILLE POWER ADMINISTRATION
CAE–20.
OMITTED

Consent Agenda—Gas and Oil

CAG–1.
DOCKET# RP97–402, 000, NATIONAL FUEL GAS SUPPLY CORPORATION
CAG–2.
DOCKET# RP97–404, 000, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
OTHER#S RP97–404, 001, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–3.
DOCKET# RP97–415, 000, IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
OTHER#S RP97–415, 001, IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
CAG–4.
DOCKET# RP97–287, 004, EL PASO NATURAL GAS COMPANY
CAG–5.
DOCKET# RP97–397, 000, EL PASO NATURAL GAS COMPANY
CAG–6.
DOCKET# RP97–407, 000, WILLIAMS NATURAL GAS COMPANY
OTHER#S RP89–183, 074, WILLIAMS NATURAL GAS COMPANY
CAG–7.
DOCKET# RP97–408, 000, TRAILBLAZER PIPELINE COMPANY
CAG–8.
DOCKET# RP97–409, 000, WYOMING INTERSTATE COMPANY, LTD.
CAG–9.
DOCKET# RP97–410, 000, WILLISTON BASIN INTERSTATE P/L CO.
CAG–10.
DOCKET# RP97–416, 000, MIGC, INC.
CAG–11.
DOCKET# PR97–6, 000, LOUISIANA INTRASTATE GAS COMPANY, L.L.C.
CAG–12.
DOCKET# PR95–3, 000, MOSS BLUFF HUB PARTNERS, L.P.
CAG–13. DOCKET# RP95–64, 002, TENNESSEE GAS PIPELINE COMPANY
OTHER#S RP96–292, 001, TENNESSEE GAS PIPELINE COMPANY
CAG–14.
DOCKET# RP96–147, 001, EQUITRANS, L.P.
CAG–15.
DOCKET# RP97–355, 001, CNG TRANSMISSION CORPORATION
CAG–16.
DOCKET# RP97–360, 000, ANR PIPELINE COMPANY
CAG–17.
DOCKET# RP96–45, 004, NORTHERN BORDER PIPELINE COMPANY
CAG–18.
DOCKET# GT95–11, 000, WILLIAMS NATURAL GAS COMPANY
OTHER#S GT95–11, 001, WILLIAMS NATURAL GAS COMPANY
CAG–19.
DOCKET# RP96–347, 003, NORTHERN NATURAL GAS COMPANY
OTHER#S RP93–206, 013, NORTHERN NATURAL GAS COMPANY
RP93–206, 015, NORTHERN NATURAL GAS COMPANY
RP96–347, 005, NORTHERN NATURAL GAS COMPANY
CAG–20.

DOCKET# RP97–19, 006, MOJAVE PIPELINE COMPANY
CAG–21.
DOCKET# RP97–290, 000, COLORADO INTERSTATE GAS COMPANY
OTHER#S RP97–290, 001, COLORADO INTERSTATE GAS COMPANY
CAG–22.
DOCKET# RP97–291, 001, PANHANDLE EASTERN PIPE LINE COMPANY
CAG–23.
DOCKET# RP97–413, 000, PANHANDLE EASTERN PIPE LINE COMPANY
CAG–24.
OMITTED
CAG–25.
DOCKET# RP85–177 ET AL., 119, TEXAS EASTERN TRANSMISSION CORPORATION
CAG–26.
DOCKET# RP97–163, 004, WESTGAS INTERSTATE, INC.
OTHER#S RP97–324, 001, WESTGAS INTERSTATE, INC.
CAG–27.
DOCKET# GP97–1, 001, ROCKY MOUNTAIN NATURAL GAS COMPANY
CAG–28.
DOCKET# RP97–16, 003, NORTHERN NATURAL GAS COMPANY
CAG–29.
DOCKET# TM97–2–59, 002, NORTHERN NATURAL GAS COMPANY
CAG–30.
DOCKET# RP97–315, 003, NORTHWEST PIPELINE CORPORATION
OTHER#S RP97–180, 001, NORTHWEST PIPELINE CORPORATION
RP97–180, 002, NORTHWEST PIPELINE CORPORATION
RP97–180, 003, NORTHWEST PIPELINE CORPORATION
RP97–180, 004, NORTHWEST PIPELINE CORPORATION
RP97–180, 005, NORTHWEST PIPELINE CORPORATION
RP97–315, 001, NORTHWEST PIPELINE CORPORATION
RP97–315, 002, NORTHWEST PIPELINE CORPORATION
CAG–31.
DOCKET# RP97–171, 006, ANR PIPELINE COMPANY
OTHER#S RP97–171, 005, ANR PIPELINE COMPANY
RP97–311, 001, ANR PIPELINE COMPANY
CAG–32.
DOCKET# RP96–393, 005, KOCH GATEWAY PIPELINE COMPANY
OTHER#S RP96–393, 004, KOCH GATEWAY PIPELINE COMPANY
CAG–33.
OMITTED
CAG–34.
DOCKET# RP97–312, 002, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
OTHER#S RP97–71, 006, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–35.
OMITTED
CAG–36.
DOCKET# RP97–102, 003, MISSISSIPPI RIVER TRANSMISSION CORPORATION
CAG–37.
DOCKET# RP96–63, 002, IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
CAG–38.
DOCKET# RP97–126, 002, IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
CAG–39.
OMITTED
CAG–40.
DOCKET# OR89–2, 011, TRANS ALASKA PIPELINE SYSTEM
OTHER#S IS89–7, 012, AMERADA HESS PIPELINE CORPORATION
IS89–8, 012, ARCO PIPELINE COMPANY
IS89–9, 012, BP PIPELINES (ALASKA), INC.
IS89–10, 012, EXXON PIPELINE COMPANY
IS89–11, 012, MOBIL ALASKA PIPELINE COMPANY
IS89–12, 012, PHILLIPS ALASKA PIPELINE CORPORATION
IS89–13, 012, UNOCAL PIPELINE COMPANY
IS96–16, 002, SADLEROCHIT PIPELINE COMPANY
OR96–14, 002, EXXON COMPANY, U.S.A. V. AMERADA HESS PIPELINE CORPORATION, ET AL.
CAG–41.
DOCKET# RP97–333, 000, CONNECTICUT NATURAL GAS CO. AND YANKEE GAS SERVICES CO. ET AL. V. IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
OTHER#S RP97–126, 000, IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
CAG–42.
DOCKET# IS94–23, 000, GAVIOTA TERMINAL COMPANY
OTHER#S IS94–37, 000, GAVIOTA TERMINAL COMPANY
IS95–35, 000, GAVIOTA TERMINAL COMPANY
IS97–12, 000, GAVIOTA TERMINAL COMPANY
OR94–5, 000, GAVIOTA TERMINAL COMPANY
CAG–43.
DOCKET# OR96–2, 000, TEXACO REFINING AND MARKETING, INC. V. SFPP, L.P.
OTHER#S OR96–10, 000, ARCO PRODUCTS COMPANY V. SFPP, L.P.
OR96–17, 000, ULTRAMAR, INC. V. SFPP, L.P.
CAG–44.
DOCKET# OR96–13, 000, ULTRAMAR, INC. V. GAVIOTA TERMINAL COMPANY
CAG–45.
DOCKET# MG96–13, 002, K N INTERSTATE GAS TRANSMISSION COMPANY
OTHER#S MG96–13, 003, K N INTERSTATE GAS TRANSMISSION COMPANY
MG96–13, 004, K N INTERSTATE GAS TRANSMISSION COMPANY
CAG–46.
DOCKET# MG97–14, 000, NATIONAL FUEL GAS SUPPLY CORPORATION
CAG–47.
DOCKET# MG97–15, 000, KERN RIVER GAS TRANSMISSION COMPANY
CAG–48.
OMITTED
CAG–49.
DOCKET# CP96–185, 002, ANR PIPELINE COMPANY
OTHER#S CP96–188, 001, GPM GAS CORPORATION
CAG–50.
DOCKET# CP96–477, 001, K N INTERSTATE GAS TRANSMISSION COMPANY
CAG–51.
OMITTED
CAG–52.
DOCKET# CP97–96, 000, KOCH GATEWAY PIPELINE COMPANY
CAG–53.
DOCKET# CP95–49, 000, TENNESSEE GAS PIPELINE COMPANY
CAG–54.
DOCKET# CP96–690, 000, NORTHERN NATURAL GAS COMPANY
CAG–55.
DOCKET# CP96–709, 000, PANHANDLE EASTERN PIPE LINE COMPANY
CAG–56.
DOCKET# CP97–143, 000, WESTERN TRANSMISSION CORPORATION
CAG–57.
DOCKET# CP96–720, 000, NATURAL GAS PIPELINE COMPANY OF AMERICA
CAG–58.
OMITTED
CAG–59.
DOCKET# CP96–347, 000, GRANITE STATE GAS TRANSMISSION, INC.
CAG–60.
DOCKET# PR97–7, 000, OVERLAND TRAIL TRANSMISSION COMPANY

Hydro Agenda

H–1.
RESERVED

Electric Agenda

E–1.
DOCKET# EC97–24, 000, NORAM ENERGY SERVICES, INC.
OTHER#S ER94–1247, 010, NORAM ENERGY SERVICES, INC.; ORDER ON PROPOSED DISPOSITION OF JURISDICTIONAL FACILITIES.
E–2.
DOCKET# EC96–19, 003, PACIFIC GAS AND ELECTRIC COMPANY, SAN DIEGO GAS & ELECTRIC COMPANY AND SOUTHERN CALIFORNIA EDISON COMPANY
OTHER#S ER96–1663, 003, PACIFIC GAS AND ELECTRIC COMPANY, SAN DIEGO GAS & ELECTRIC COMPANY AND SOUTHERN CALIFORNIA EDISON COMPANY; ORDER ADDRESSING (PROPOSAL TO IMPLEMENT) PHASE II OF THE CALIFORNIA RESTRUCTURING.
E–3.
DOCKET# EC97–7, 000, ATLANTIC CITY ELECTRIC COMPANY AND DELMARVA POWER & LIGHT COMPANY; ORDER ON APPLICATION FOR AUTHORIZATION OF A PROPOSED MERGER.
E–4.
DOCKET# OA96–18, 000, ALLEGHENY POWER SYSTEM, INC.
OTHER#S OA96–3, 000, ST. JOSEPH LIGHT & POWER COMPANY
OA96–4, 000, KANSAS CITY POWER & LIGHT COMPANY

OA96–9, 000, PACIFICORP
OA96–10, 000, TAPOCO, INC.
OA96–12, 000, YADKIN, INC.
OA96–13, 000, PECO ENERGY COMPANY
OA96–16, 000, IDAHO POWER COMPANY
OA96–19, 000, NORTHEAST UTILITIES SERVICE COMPANY
OA96–20, 000, WISCONSIN POWER & LIGHT COMPANY
OA96–21, 000, PUBLIC SERVICE COMPANY OF COLORADO
OA96–27, 000, SOUTHERN COMPANY SERVICES, INC. AND ALABAMA POWER COMPANY
OA96–28, 000, PACIFIC GAS & ELECTRIC COMPANY
OA96–33, 000, SOUTHWESTERN PUBLIC SERVICE COMPANY
OA96–36, 000, CENTRAL ILLINOIS LIGHT COMPANY
OA96–39, 000, FLORIDA POWER & LIGHT COMPANY
OA96–40, 000, MONTANA-DAKOTA UTILITIES COMPANY
OA96–42, 000, MIDAMERICAN ENERGY COMPANY
OA96–44, 000, UGI UTILITIES, INC.
OA96–46, 000, DUKE POWER COMPANY
OA96–47, 000, NORTHERN INDIANA PUBLIC SERVICE COMPANY
OA96–49, 000, SOUTH CAROLINA ELECTRIC & GAS COMPANY
OA96–53, 000, CENTRAL VERMONT PUBLIC SERVICE CORPORATION
OA96–56, 000, DUQUESNE LIGHT COMPANY
OA96–64, 000, DAYTON POWER & LIGHT COMPANY
OA96–66, 000, ILLINOIS POWER COMPANY
OA96–67, 000, MONTAUP ELECTRIC COMPANY
OA96–73, 000, FLORIDA POWER CORPORATION
OA96–74, 000, NEW ENGLAND POWER COMPANY
OA96–75, 000, BLACK HILLS POWER AND LIGHT COMPANY
OA96–76, 000, SOUTHERN CALIFORNIA EDISON COMPANY
OA96–77, 000, CONSUMERS ENERGY COMPANY
OA96–79, 000, WISCONSIN PUBLIC SERVICE CORPORATION
OA96–80, 000, PUBLIC SERVICE ELECTRIC & GAS COMPANY
OA96–109, 000, POTOMAC ELECTRIC POWER COMPANY
OA96–114, 000, GPC SERVICE CORPORATION
OA96–115, 000, MT. CARMEL PUBLIC UTILITIES COMPANY
OA96–116, 000, TAMPA ELECTRIC COMPANY
OA96–117, 000, SOUTHERN INDIANA GAS & ELECTRIC COMPANY
OA96–122, 000, MAINE PUBLIC SERVICE COMPANY
OA96–125, 000, IES UTILITIES, INC.
OA96–137, 000, PORTLAND GENERAL ELECTRIC COMPANY
OA96–139, 000, SAN DIEGO GAS & ELECTRIC COMPANY
OA96–142, 000, PENNSYLVANIA POWER & LIGHT COMPANY
OA96–155, 000, MIDWEST ENERGY, INC.
OA96–156, 000, BALTIMORE GAS & ELECTRIC COMPANY
OA96–158, 000, ENTERGY SERVICES, INC.
OA96–159, 000, ATLANTIC CITY ELECTRIC COMPANY
OA96–161, 000, PUGET SOUND POWER & LIGHT COMPANY
OA96–162, 000, WASHINGTON WATER POWER COMPANY
OA96–163, 000, LOCKHART POWER COMPANY
OA96–164, 000, MINNESOTA POWER & LIGHT COMPANY
OA96–165, 000, DELMARVA POWER & LIGHT COMPANY
OA96–166, 000, COMMONWEALTH EDISON COMPANY
OA96–167, 000, COMMONWEALTH ELECTRIC COMPANY
OA96–169, 000, CINERGY SERVICES, INC.
OA96–171, 000, UNITED ILLUMINATING COMPANY
OA96–178, 000, CAMBRIDGE ELECTRIC LIGHT COMPANY
OA96–182, 000, CONSUMERS ENERGY COMPANY
OA96–183, 000, AMERICAN ELCTRIC POWER SERVICE CORPORATION
OA96–184, 000, CITIZENS UTILITIES COMPANY
OA96–186, 000, UTILICORP UNITED INC.
OA96–188, 000, NEVADA POWER COMPANY
OA96–189, 000, MAINE ELECTRIC POWER COMPANY
OA96–190, 000, OHIO VALLEY ELECTRIC CORPORATION
OA96–191, 000, BANGOR HYDRO-ELECTRIC COMPANY
OA96–193, 000, KENTUCKY UTILITIES COMPANY
OA96–196, 000, WISCONSIN ELECTRIC POWER COMPANY
OA96–199, 000, MONTANA POWER COMPANY
OA96–202, 000, PUBLIC SERVICE COMPANY OF NEW MEXICO
OA96–203, 000, WESTERN RESOURCES, INC.
OA96–207, 000, NORTHWESTERN PUBLIC SERVICE COMPANY
OA96–208, 000, LOUISVILLE GAS AND ELECTRIC COMPANY
OA96–210, 000, ORANGE AND ROCKLAND UTILITIES, INC.
OA96–213, 000, INTERSTATE POWER COMPANY; ORDER ON COMPLIANCE TARIFF RATE ISSUES AND IMPLEMENTATION PROCEDURES FOR 74 OPEN ACCESS TRANSMISSION TARIFFS FILED IN COMPLIANCE WITH ORDER 888.

E–5.
DOCKET# EL97–40, 000, INDEPENDENT POWER PRODUCERS OF NEW YORK, INC.; ORDER ON PETITION FOR DECLARATORY ORDER AND TO INITIATE PURPA ENFORCEMENT ACTION.

E–6.
DOCKET# SC97–2, 000, CITY OF LAS CRUCES, NEW MEXICO; ORDER ON PETITION FOR DECLARATORY ORDER CONCERNING POTENTIAL STRANDED COST LIABILITY.

E–7.
OMITTED

E–8.
DOCKET# EL97–18, 000, SOUTHWESTERN PUBLIC SERVICE COMPANY V., EL PASO ELECTRIC COMPANY; ORDER ON COMPLAINT REQUESTING TRANSMISSION SERVICE.

Oil and Gas Agenda

I. PIPELINE RATE MATTERS

PR–1.
DOCKET# RP97–346, 000, EQUITRANS, L.P.
OTHER#S TM97–3–24, 000, EQUITRANS, L.P.; ORDER ON TARIFF SHEETS.

PR–2.
DOCKET# RP97–406, 000, CNG TRANSMISSION CORPORATION
OTHER#S RP96–144, 000, CNG TRANSMISSION CORPORATION; ORDER ON TARIFF SHEETS.

PR–3.
DOCKET# RP97–411, 000, SEA ROBIN PIPELINE COMPANY; ORDER ON TARIFF SHEETS.

PR–4.
DOCKET# RP94–365, 000, WILLIAMS NATURAL GAS COMPANY; ORDER ON INITIAL DECISION.

PR–5.
DOCKET# RP93–109, 011, WILLIAMS NATURAL GAS COMPANY; ORDER ON REHEARING.

PR–6.
DOCKET# RP97–369, 000, PUBLIC SERVICE COMPANY OF COLORADO AND CHEYENNE LIGHT FUEL AND POWER COMPANY
OTHER#S GP97–3, 000, AMOCO PRODUCTION COMPANY, ANADARKO PET-ROLEUM CORPORATION, MOBIL OIL CORPORATION AND OXY USA, INC., ET AL.
GP97–4, 000, KANSAS SMALL PRODUCER GROUP
GP97–5, 000, MESA OPERATING COMPANY; ORDER ON ADJUSTMENT AND REFUNDS.

PR–7.
DOCKET# RP95–197, 023, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
OTHER#S RP95–197, 024, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
RP96–44, 005, TRANSCONTINENTAL GAS PIPE LINE CORPORATION; ORDER ON INITIAL DECISION.

II. PIPELINE CERTIFICATE MATTERS

PC–1.
DOCKET# CP96–647, 000, GREAT LAKES GAS TRANSMISSION LIMITED PARTNERSHIP; PROPOSAL TO CONSTRUCT AND OPERATE MAINLINE LOOPING AND ADDITIONAL COMPRESSION.

PC–2.
OMITTED

PC–3.
DOCKET# CP96–248, 001, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
OTHER#S CP96–248, 000, PORTLAND NATURAL GAS TRANSMISSION SYSTEM

CP96–248, 002, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CP96–248, 003, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CP96–248, 004, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CP96–249, 000, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CP96–249, 001, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CP96–249, 002, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CP96–249, 003, PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CP96–249, 004, PORTLAND NATURAL GAS TRANSMISSION SYSTEM; PROPOSAL TO CONSTRUCT AND OPERATE NEW PIPELINE SYSTEM.

PC–4.
DOCKET# CP96–178, 001, MARITIMES & NORTHEAST PIPELINE, L.L.C.
OTHER#S CP96–178, 000, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP96–178, 002, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP96–178, 003, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP97–238, 000, PORTLAND NATURAL GAS TRANSMISSION SYSTEM AND MARITIMES & NORTHEAST PIPELINE, L.L.C.; PROPOSALS (INCLUDING JOINT PROPOSAL) TO CONSTRUCT NEW PIPELINE SYSTEMS.

PC–5.
DOCKET# CP97–168, 000, ALLIANCE PIPELINE L.P.
OTHER#S CP97–169, 000, ALLIANCE PIPELINE L.P.
CP97–177, 000, ALLIANCE PIPELINE L.P.
CP97–178, 000, ALLIANCE PIPELINE L.P.; PROPOSAL TO CONSTRUCT AND OPERATE NEW PIPELINE SYSTEM.

PC–6.
DOCKET# CP95–194, 002, NORTHERN BORDER PIPELINE COMPANY
OTHER#S CP95–194, 000, NORTHERN BORDER PIPELINE COMPANY
CP95–194, 001, NORTHERN BORDER PIPELINE COMPANY
CP95–194, 003, NORTHERN BORDER PIPELINE COMPANY; PROPOSED EXPANSION AND EXTENSION OF NORTHERN BORDER SYSTEM.

PC–7.
DOCKET# CP96–27, 000, NATURAL GAS PIPELINE COMPANY OF AMERICA
OTHER#S CP96–27, 001, NATURAL GAS PIPELINE COMPANY OF AMERICA; PROPOSED EXPANSION OF SYSTEM; ALTERNATIVE TO PC–6.

PC–8.
DOCKET# CP97–294, 000, NATURAL GAS PIPELINE COMPANY OF AMERICA; PROPOSAL TO CONSTRUCT AND OPERATE EXPANSION FACILITIES.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19980 Filed 7–24–97; 4:22 pm]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5864–7]

Pesticides; OMB Review of Information Collection Activities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this notice announces that the Information Collection Requests (ICR) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment pursuant to 5 CFR 1320.12. The ICRs describe the nature of the information collection and expected cost and burden; where appropriate, they include the actual data collection instrument. A **Federal Register** notice requesting public comment on the renewals of these ICRs was published on April 16, 1997 (62 FR 18600). EPA did not receive any comments.

DATES: Comments must be submitted on or before August 28, 1997.

FOR FURTHER INFORMATION OR A COPY CALL: Sandy Farmer at EPA, (202) 260–2740, or e-mail: farmer.sandy@epamail.epa.gov. Please refer to the appropriate EPA and OMB ICR number as indicated below.

SUPPLEMENTARY INFORMATION: EPA has forwarded the following three ICRs to OMB for review pursuant to 5 CFR 1320.12, requesting an extension of the currently approved information collection activities contained in each ICR.

1. *Title:* Notice of Supplemental Distribution of a Registered Pesticide Product.

ICR No.: OMB Control No. 2070–0044; EPA ICR No. 0278.06.

Current Expiration Date: August 31, 1997.

Abstract: Under section 3(e) of the Federal, Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, products which ''have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide, and additional names and labels shall be added to the registration by supplemental statements.'' This information collection activity is the completion and submission of the supplemental statements referred to in FIFRA section 3(e). A standard form (EPA Form 8570–5) is provided for the applicant's convenience in providing the necessary information (name and address of the basic product registrant and of the distributor, and the name and EPA Registration Number of the product involved in the distributorship agreement) to the EPA. The pesticide registrant notifies EPA, with the use of this form, that it has entered into an agreement with a second company which will distribute the registrant's product under the second company's name and product name.

Burden Statement: The annual respondent burden for the supplemental registration of a pesticide product is estimated to average 15 minutes per response. This estimate includes the time needed for: planning activities, creating information, gathering information, processing, compiling, and reviewing information for accuracy, recording, disclosing or displaying the information, and storing, filing, and maintaining the data. There is no third party notification included in this ICR.

Respondents/Affected Entities: Parties affected by this information collection are registrants of pesticide products.

Estimated No. of Respondents: 6,000.

Estimated Total Annual Burden on Respondents: 1,500 hours.

Frequency of Collection: Once per event.

2. *Title:* FIFRA Reregistration Fees.

ICR No.: OMB Control No. 2070–0101; EPA ICR No. 1495.04.

Expiration Date: August 31, 1997.

Abstract: This reporting and recordkeeping activity, mandated by FIFRA, authorizes the collection of reregistration fees from pesticide registrants. These fees (with waivers and exemptions) apply to the pesticide active ingredients registered under FIFRA before November 1, 1984, which are subject to reregistration. The 1988 amendments to FIFRA established one-time reregistration fees and required EPA to apportion those fees on the basis of market share. Without information on market share, exempt status of registrants, and eligibility for small business waivers, the Agency would not be able to fully implement the statutory requirements of FIFRA or to collect the total amount of required fees, and thus could encounter a shortfall in budget projections.

A small portion of the registrant population (those maintaining registrations for certain biological pesticides) was granted reregistration fee deferrals extending the time for payment of reregistration fees to up to five years (1994–1999). These registrants will be involved only in the reregistration fee deferral information collection process. This renewal is for

the few remaining biological pesticide cases.

The data required under this information collection will be generated through the use of three forms: the Reregistration Fee Apportionment Form, the Small Business Waiver Certification Form, and the Biological Active Ingredient Sales Reporting Form.

Burden Statement: The annual respondent burden for the FIFRA Reregistration Fees information collection activity is estimated to average 3.7 hours per response. This estimate includes the time needed for: planning activities, creating information, gathering information, processing, compiling, and reviewing information for accuracy, recording, disclosing or displaying the information, and storing, filing, and maintaining the data. A Small Business Waiver Certification Form was developed out of a concern for the burden on small entities. Thus, eligible small entities will qualify for fee waivers. There is no third party notification included in this ICR.

Respondents/Affected Entities: Parties affected by this information collection activity are manufacturers of pesticide chemicals who have not previously paid these reregistration fees.

Estimated No. of Respondents: 50.

Estimated Total Annual Burden on Respondents: 185 hours.

Frequency of Collection: Once per event.

3. *Title:* Pesticide Product Registration Maintenance Fees.

ICR No.: OMB Control No. 2070–0100; EPA ICR No. 1214.04.

Expiration Date: September 30, 1997.

Abstract: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended in 1988 makes provisions for registration maintenance fees under section 4(I)(5). These fees apply to all products registered under section 3 and section 24(c) of FIFRA. The fees are to be paid annually for each product registered and are payable on January 15 of each year.

The information collected is used by the Agency to ensure that the fees prescribed by FIFRA have been paid by each registrant. The information is also used to adjust OPP's computer files to reflect changes in the status of registrations resulting from registrant responses. In order to provide an efficient system to bill, collect, and account for registration maintenance fees, the Agency has used a filing form which is sent to all registrants of currently active products.

Burden Statement: The annual respondent burden for Pesticide Product Registration Maintenance Fees is estimated to average 0.94 hours per response. This estimate includes the time needed for: planning activities, creating information, gathering information, processing, compiling, and reviewing information for accuracy, recording, disclosing or displaying the information, and storing, filing, and maintaining the data. There is no third party notification included in this ICR.

Respondents/Affected Entities: Parties affected by this information collection activity are registrants of pesticide products holding currently active registrations under FIFRA section 3 and section 24(c).

Estimated No. of Respondents: 2,117 respondents.

Estimated Total Annual Burden on Respondents: 1,990 hours.

Frequency of Collection: Once per year.

No person is required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for any regulations related to these ICRs are displayed in 40 CFR part 9.

Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to the following addresses: Ms. Sandy Farmer, U.S. Environmental Protection Agency, Regulatory Information Division (2137), 401 M Street, S.W., Washington, D.C. 20460; and Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, N.W., Washington, D.C. 20503. Please be sure to refer to the appropriate EPA and OMB numbers referenced for the ICRs in any correspondence.

Dated: July 23, 1997.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 97–19882 Filed 7–28–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5864–6]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Performance Evaluation Studies on Water and Wastewater Laboratories

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Performance Evaluation Studies on Water and Wastewater Laboratories, OMB #2080–0021, to expire on October 31, 1997. The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 28, 1997.

FOR FURTHER INFORMATION OR A COPY CALL: Sandy Farmer at EPA, (202) 260–2740, and refer to EPA ICR No. 234.06.

SUPPLEMENTARY INFORMATION:

Title: Performance Evaluation Studies on Water and Wastewater Laboratories (OMB Control No. 2080–0021; EPA ICR No. 234.06) expiring 10/31/97. This is a request for extension of a currently approved collection.

Abstract: The U.S.EPA receives analytical results on drinking waters and wastewaters from a variety of laboratories and must rely on these data as a primary basis for many of its regulatory decisions. As a consequence, it has become very important to have an objective demonstration that the contributing laboratories are capable of producing valid data. The Laboratory Performance Evaluation Studies are designed to fulfill this need to document and improve the quality of analytical data for certain critical analyses within drinking water, major point-source discharge and ambient water quality samples. Participation in Water Pollution (WP) studies that relate to wastewater analyses, and Water Supply (WS) studies that relate to drinking water analyses, is only mandated by the U.S.EPA for those laboratories that are receiving federal funds to do such analyses, however successful participation in these studies is often required by states that certify laboratories for water and wastewater analyses. Participation in the Discharge Monitoring Report—Quality Assurance (DMR–QA) studies is mandatory for those designated wastewater dischargers who are doing self-monitoring analyses required under a National Pollutant Discharge Elimination System (NPDES) permit. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The **Federal Register** notice required

under 5 CFR 1320.8(d), soliciting comments on this collection of information was published in 4/28/97 (62 FR 22940); One comment was received.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to total 124,243 hours/year, as follows:

Type of study	Studies/ year	Resp./study	Avg. burden hours/resp.	Total annual respondent burden (hours)
Water Pollution Studies	2	3,262.5	6.10	39,802
DMR–QA Studies (chemistry data)	1	6,112	4.37	26,710
DMR–QA Studies (toxicity data)	1	300	66.2	19,860
Water Supply Studies (chemistry data)	2	2,202.5	7.87	34,667
Water Supply Studies (micro. data)	2	300	5.34	3,204
Total	.....	.....	.....	124,243

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected entities: wastewater labs, NPDES permittees and toxicity labs, and water chemistry and microbiological labs.

Estimated Number of Respondents (per year): 6,525 wastewater labs, 6,112 permittees, 300 tox labs and 5,005 water labs (chem + micro).

Frequency of Response: two studies per year, except for the annual DMR–QA (NPDES) study.

Estimated Total Annual Hour Burden: 124,243 hours.

Estimated Total Annualized Cost Burden: $5,321,063.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR number 234.06 and OMB control number 2080–0021 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OPPE Regulatory Information Division (2137), 401 M Street, SW., Washington, DC 20460

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

Dated: July 23, 1997.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 97–19886 Filed 7–28–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5865–2]

Meeting of the Local Government Advisory Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The theme of the next meeting of the Local Government Advisory Committee is organization, structure and future activities of the LGAC. The committee will also continue work on outstanding business and vote on the final report of the Tools for Local Decision-Makers Subcommittee. The committee will hear presentations on the new EPA Region 3 Small Communities Tool Kit available on the WEB, and on the new EPA Clean Air Standards. The Roles and Responsibilities and the Tools for Local Decision-Makers Subcommittees will meet in subcommittee sessions, to continue their ongoing projects, but most of the time will be spent in full committee meetings.

From 3:00–3:15 p.m. on the 14th, the Committee will hear comments from the public. Each individual or organization wishing to address the Committee will be allowed three minutes. Please contact the Designated Federal Officer (DFO) at the number listed below to schedule agenda time. Time will be allotted on a first come, first serve basis.

This is an open meeting and all interested persons are invited to attend. Meeting minutes will be available after the meeting and can be obtained by written request from the DFO. Members of the public are requested to call the DFO at the number listed below if planning to attend so that arrangements can be made to comfortably accommodate attendees as much as possible. However, seating will be on a first come, first serve basis.

DATES: The meeting will begin at 8:30 a.m. on Thursday, August 14th and conclude at 4:00 p.m. on Friday, August 15, 1997.

ADDRESSES: The meeting will be held at the Wyndham Bristol Hotel located at 2430 Pennsylvania Avenue NW, Washington, DC.

Requests for Minutes and other information can be obtained by writing to 401 M Street, S.W. (1502), Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: The DFO for this Committee is Denise Zabinski Ney. She is the point of contact for information concerning any Committee matters and can be reached by calling (202) 260–0419.

Dated: July 21, 1997.

Denise Zabinski Ney,

Designated Federal Officer, Local Government Advisory Committee.

[FR Doc. 97–19939 Filed 7–28–97; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to

comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments concerning an information collection titled ''Application for Consent to Reduce or Retire Capital.''

DATES: Comments must be submitted on or before September 29, 1997.

ADDRESSES: Interested parties are invited to submit written comments to Steven F. Hanft, FDIC Clearance Officer, (202) 898–3907, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street N.W., Washington, D.C. 20429. Comments may be hand-delivered to the guard station at the rear of the 17th Street building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m. (Fax number (202) 808–3838; Internet address: comments@fdic.gov]). All comments should refer to ''Application for Consent to Reduce or Retire Capital.''

A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Steven F. Hanft, at the address identified above.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collection of information:

Title: Application for Consent to Reduce or Retire Capital.

OMB Number: 3064–0079.

Frequency of Response: Occasional.

Estimated Total Annual Responses: 125.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden: 125 hours.

General Description Of the Collection: Section 18(i) of the Federal Deposit Insurance Act (12 U.S.C. 1828(i)) states that no insured state nonmember bank shall, without the prior consent of the FDIC, reduce the amount or retire any part of its common or preferred capital stock, or retire any part of its capital notes or debentures. In granting or withholding consent under section 18(i) of the FDI Act, the FDIC is required to consider the following: (a) the financial history and condition of the bank, (b) the adequacy of its capital structure, (c) its future earnings prospects (d) the general character and fitness of its management, (e) the convenience and needs of the community to be served, and (f) whether or not its corporate powers are consistent with the purpose of the Act. To carry out this statutory responsibility, the FDIC requires the banks it supervises to submit letter applications that convey information about planned capital reductions. The FDIC evaluates the information contained in an application and makes a decision to grant or withhold consent based on the statutory considerations.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments submitted in response to this notice also will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record.

Dated at Washington, D.C., this 23rd day of July 1997.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 97–19881 Filed 7–28–97; 8:45 am]

BILLING CODE 6714–01–M

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Submission to OMB Under Delegated Authority

Background

Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT:

Chief, Financial Reports Section—Mary M. McLaughlin—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3829)

OMB Desk Officer—Alexander T. Hunt—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503 (202-395-7860)

Final approval under OMB delegated authority of the extension for three years, without revision, of the following report:

1. Report title: Request for Proposal (RFP); Request for Price Quotations (RFPQ)

Agency form number: n/a

OMB Control number: 7100-0180

Frequency: on occasion

Reporters: vendors and suppliers

Annual reporting hours: 7,610

Estimated average hours per response: 20.0 (RFP); 0.5 (RFPQ)

Number of respondents: 248 (RFP); 5,300 (RFPQ)

Small businesses are affected.

General description of report: This information collection is required to obtain or retain a benefit (12 U.S.C. sections 243, 244, and 248) and is not given confidential treatment unless a respondent requests that portions of the information be kept confidential and the Board grants the request pursuant to the applicable exemptions provided by the Freedom of Information Act (5 U.S.C. section 552).

Abstract: The Federal Reserve Board uses the RFP and the RFPQ as needed to obtain competitive proposals and contracts from approved vendors of goods and services. Depending upon the goods and services for which the Federal Reserve Board is seeking competitive bids, the respondent is requested to provide either prices for providing the goods or services (RFPQ) or a document covering not only prices, but also the means of performing a particular service and a description of the qualification of the staff who will perform the service (RFP). The Board staff uses this information to analyze the proposals and to select the best offer.

Board of Governors of the Federal Reserve System, July 24, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97-19947 Filed 7-28-97; 8:45AM]

Billing Code 6210-01-F

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 12, 1997.

A. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Jasper Banking Company Second Amended and Restated Employee Stock Ownership Stock Bonus Plan (ESOP), Jasper, Georgia; to acquire an additional 1 percent for a total of 10 percent of the voting shares of JBC Bancshares, Inc., Jasper, Georgia.

B. Federal Reserve Bank of San Francisco (Pat Marshall, Manager of Analytical Support, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. John Isaac Bloomberg, Park City, Utah; to acquire a total of 3.20 percent of the voting shares of Draper BanCorp, Draper, Utah, and thereby indirectly acquire Draper Bank and Trust, Draper, Utah. Notificant is part of a group that owns 50 percent of Draper.

Board of Governors of the Federal Reserve System, July 23, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–19863 Filed 7-28-97; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 22, 1997.

A. Federal Reserve Bank of New York (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. ALBANK Financial Corporation, Albany, New York; to become a bank holding company by acquiring 100 percent of the voting shares of ALBANK Commercial, Albany, New York.

In connection with this application, Applicant also has applied to retain its wholly-owned subsidiary, ALBANK, FSB, Albany, New York, pursuant to § 225.28(b)(4) of the Board's Regulation Y.

B. Federal Reserve Bank of Richmond (A. Linwood Gill III, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. NationsBank Corporation, Charlotte, North Carolina; to acquire 100 percent of the voting shares of NationsBank, National Association (Glynn County), Brunswick, Georgia, which is the proposed successor by charter conversion of First Federal Savings Bank of Brunswick, Georgia, Brunswick, Georgia, a subsidiary of NationsBank Corporation.

C. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. The Colonial BancGroup, Inc., Montgomery, Alabama; to merge with Dadeland Bancshares, Inc., Miami, Florida, and thereby indirectly acquire Dadeland Bank, Miami, Florida.

In connection with this application, Applicant also has applied to acquire Dadeland Software Services, Inc., Miami, Florida, and thereby engage in data processing activities, pursuant to § 225.28(b)(14) of the Board's Regulation Y.

2. Murfreesboro Bancorp, Inc., Murfreesboro, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Bank of Murfreesboro, Murfreesboro, Tennessee (in organization).

D. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. Community Financial Corp, Olney, Illinois; to acquire 100 percent of the voting shares of Egyptian Bancshares, Inc., Carrier Mills, Illinois, and thereby indirectly acquire The Egyptian State Bank, Carrier Mills, Illinois, and Saline County State Bank, Stonefort, Illinois.

Board of Governors of the Federal Reserve System, July 23, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–19862 Filed 7-28-97; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 22, 1997.

A. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Rockdale National Bankshares, Inc., Conyers, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Rockdale National Bank, Conyers, Georgia (in organization).

Board of Governors of the Federal Reserve System, July 24, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–19946 Filed 7-28-97; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 11, 1997.

A. Federal Reserve Bank of New York (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001, **or Federal Reserve Bank of Chicago** (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. Royal Bank of Canada, Montreal, Canada, and Stitching Prioriteir ABN AMRO Holding, Amsterdam, The Netherlands; Stichting Administratiekantoor ABN AMRO Holding, Amsterdam, The Netherlands; ABN AMRO Holding, N.V., Amsterdam, The Netherlands; ABN AMRO Bank, N.V., Amsterdam, The Netherlands; and ABN AMRO North America, Inc., Chicago, Illinois; to acquire through Integrion Financial Network, LLC, Atlanta, Georgia, and thereby indirectly acquire certain assets and liabilities of VISA Interactive, Inc., and thereby engage in providing data processing and data transmission services, pursuant to § 225.28(b)(14) of the Board's Regulation Y. These activities will be conducted worldwide.

Board of Governors of the Federal Reserve System, July 23, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–19864 Filed 7-28-97; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Government in the Sunshine Meeting

TIME AND DATE: 11:00 a.m., Monday, August 4, 1997.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: July 25, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–20090 Filed 7–25–97; 3:18 pm]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 07/07/97 AND 07/18/97

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
SW Centrifugal, Inc., John H. Culling, Carondelet Foundry Company	97–2504	07/07/97
Paul P. Lehr and Elaine Lehr (Husband and Wife), Equity Holdings, Limited, The Parts House Acquisition Corporation	97–2505	07/07/97
John W. Kluge, Ralph J. Roberts, Comcast Publishing Holdings Corporation	97–2550	07/07/97
CRH, plc, Roger J. Ciapara, RSI Wholesale of Grand Rapids, Inc.	97–2571	07/07/97
Financial Holding Corporation, Ohio Casualty Corporation. The Oil Life insurance Company	97–2581	07/07/97
Dennis M. Langley, Dennis M. Langley, Syenergy Pipeline Co., L.P	97–2583	07/07/97

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 07/07/97 AND 07/18/97—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
Golder, Thoma, Cressey, Rauner Fund V, L.P., Arkansas Best Corporation, Cardinal Freight Carriers, Inc	97–2586	07/07/97
Unitrin, Inc., The Reliable Life Insurance Company, The Reliable Life Insurance Company	97–2594	07/07/97
Heartland Express, Inc., Samuel T. Easley, A & M Express, Inc	97–2598	07/07/97
Emerson Electric Co., Bessemer Securities LLC, Metropolitan International, Inc	97–2610	07/07/97
Hicks, Muse, Tate & Furst Equity Fund III, L.P., Menlo F. Smith, Ameron Broadcasting, Inc	97–2611	07/07/97
Pratt Family Holdings Trust, Mr. John L. Bell, Bell Holdings, Inc	97–2612	07/07/97
Eli Lilly and Company, Millennium Pharmaceuticals, Inc., Millennium BioTherapeut- ics, Inc	97–2614	07/07/97
Park-Ohio Industries, Inc., Arden Industrial Products, Inc., Arden Industrial Products, Inc,	97–2618	07/07/97
John J. Taylor, III, Salvatore A. Italiano, Anthony Distributors, Inc. Anthony Distributing Co	97–2625	07/07/97
Anheuser-Busch Companies, Inc., Widmer Brothers Brewing Company, Widmer Brothers Brewing Company	97–2680	07/07/97
Saurer AG, Andal Corp., Multi-Arc Inc	97–2541	07/08/97
Willis S. McLeese (a Canadian national), Tamrock Oy (a Finnish corporation), Piney Creek III, LLC; Mid-Atlantic Energy of PA, Inc	97–2574	07/08/97
KKR 1996 Fund, L.P., Strata Associates L.P., Evenflo & Spalding Holdings Corporation	97–2646	07/08/97
British Telecommunications plc, MCI Communications Corporation, MCI Communications Corporation	97–0678	07/09/97
United News & Media, plc (a British company), Jessica Brackman, FPG International Corporation	97–2573	07/09/97
DLJ Merchant Banking Partners II, L.P., DecisionOne Holdings Corp., DecisionOne Holdings Corp	97–2601	07/09/97
Metroplitan Life Insurance Company, DCV Holdings, Inc., DCV Holdings, Inc	97–2617	07/09/97
Comsource Independent Foodservice Companies, Inc., EMCO Foodservice Systems, Inc., EMCO Foodservice Systems, Inc	97–2626	07/09/97
Saint Luke's Hospital of Kansas City, Mid-America Health Partners, Inc., Mid-America Health Partners, Inc	97–2638	07/09/97
Atlas Copco, A.B. or Prime Service, Inc., Dennis R. Pekkola, Arrow Rentals & Sales, Inc	97–2651	07/09/97
Atlas Copco, A.B. or Prime Service, Inc., Les M. Mombert, Arrow Rentals & Sales, Inc	97–2652	07/09/97
Parker-Hannifin Corporation, Kenneth Sawyer, EWAL Manufacturing Company, MKB Leasing	97–2654	07/09/97
SGL Carbon AG, Hitco Holdings, L.P., Hitco Technologies, Inc	97–2682	07/09/97
Apollo Investment Fund III, L.P., SMT Health Services Inc., SMT Health Services Inc	97–2695	07/09/97
Chimilgen Corporation d/b/a CGF Health System, Buffalo General Health System, Buffalo General Health System	97–1715	07/10/97
Chimilgen Corporation d/b/a CGF Health System, Millard Fillmore Health System, Inc., Millard Fillmore Health System, Inc	97–1716	07/10/97
Fresenius Aktiengesellschaft, Michael J. Bruce, Wake Dialysis Clinic, Inc.; Heritage Medical Supply, Inc	97–2689	07/10/97
Rational Sofware Corporation, Pure Atria Corporation, Pure Atria Corporation	97–1984	07/11/97
Thayer Equity Investors III, L.P., ITC Holding Company, Inc., InterServ Services Corporation	97–2570	07/11/97
Donald J. Larson, Concentra Managed Care, Inc., Concentra Managed Care, Inc	97–2602	07/11/97
Lois E. Silverman, Concentra Managed Care, Inc., Concentra Managed Care, Inc	97–2602	07/11/97
Mellon Bank Corporation, Bankers Trust New York Corporation, Bankers Trust Company/Assets	97–2631	07/11/97
Republic Industries, Inc., Ronald M. Salhany, Gulf Management, Inc	97–2639	07/11/97
Ronald M. Salhany, Republic Industries, Inc., Republic Industries, Inc	97–2640	07/11/97
Republic Industries, Inc., John A. Rosatti, Hollywood Imports Limited, Inc	97–2641	07/11/97
Intel Corporation, CNET, Inc., CNET, Inc	97–2649	07/11/97
ABM Industries Incorporated, Ogden Corporation, Ogden Corporation	97–2655	07/11/97
Iowa Health System, Finley Tri-States Health Group, Inc., Finley Tri-States Health Group, Inc	97–2657	07/11/97
Summit Ventures IV, L.P., Theresa Stone Pan & Jing Jong Pan, E-Tek Dynamics, Inc	97–2670	07/11/97
LG&E Energy Corp., Big Rivers Electric Corporation, Debtor-in possession, Big Rivers Electric Corporation	97–2734	07/11/97
General Motors Corporation, Integon Corporation, Integon Corporation	97–2688	07/14/97
Fred Meyer Inc., Fox Jewelry Company, Fox Jewelry Company	97–2691	07/14/97
Sequa Corporation, W.R. Grace & Co., W.R. Grace & Co	97–2693	07/14/97
Moore Corporation Limited, Robert J. Benson, The Phoenix Group, Inc., Phoenix Global Marketing, Inc	97–2709	07/14/97
Herman Sarkowsky, Chas. H. Lilly Co., (The), Chas. H. Lilly Co., (The),	97–2712	07/14/97
Bagel Store Development Funding, LLC, Bagel Store Development Funding, LLC, Noah's Bay Area Bagels, LLC, Mayfair Bagels, LLC	97–2725	07/14/97
Paul G. Allen, Kenneth E. Behring, Seattle Seahawks, Inc	97–2726	07/14/97
Kirtland Capital Partners II, L.P., American Acquisition Partners, Ltd., R. Tape Corporation	97–2744	07/14/97
Safety Components International, Inc., Collins & Aikman Corporation, JPS Automotive, L.P., Collins & Aikman Products Co	97–2745	07/14/97
San Faustin N.V., Three Cities Fund II, L.P., Salem Furnance Co	97–2558	07/15/97
A.H. Belo Corporation, Press-Enterprise Company, Press-Enterprise Company	97–2579	07/15/97
DLJ Merchant Banking Partners II, L.P., Quaker Holding Co., Quaker Holding Co	97–2600	07/15/97
Kelso Investment Associates IV, L.P., Metapoint Partners Fund-II, L.P., Marathon Power Technologies Company	97–2675	07/15/97
Wallace Computer Services, Inc., Donald Moran, Moran Printing Company	97–2692	07/15/97
PalEx, Inc., Diane Ekedahl, Somona Pacific Company and Salinas Pacific Company	97–2696	07/15/97
Stephen R. Smith, New RES, Inc., New RES, Inc	97–2697	07/15/97
Kenny A. Troutt, New RES, Inc., New RES, Inc	97–2698	07/15/97
William A. Casner, New RES, Inc., New RES, Inc	97–2699	07/15/97
Cablevision Systems Corporation, ITT Corporation, ITT Flight Operations, Inc	97–2702	07/15/97
McLeod USA Incorporated, Richard Anthony Lumpkin, Consolidated Communications Inc	97–2704	07/15/97
Richard A. Lumpkin, McLeod USA Incorporated, McLeod USA Incorporated	97–2705	07/15/97
ServiceMaster Limited Partnership, Rollins, Inc., Rollins, Inc./Assets	97–2706	07/15/97
Nelson Peltz, Ocean View Capital, Inc., Ocean View Capital, Inc	97–2707	07/15/97
SIG plc, Edgar Nullmeier, Distribution International	97–2713	07/15/97
SIG plc, Russell A. Werme, Jr., Distribution International	97–2714	07/15/97

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 07/07/97 AND 07/18/97—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
SIG plc, R.L. Anderson, Jr., Distribution International	97–2715	07/15/97
Leo J. Hindery, Jr., Tele-Communications, Inc., Tele-Communications, Inc	97–2719	07/15/97
SAFECO Corporation, Lincoln National Corporation, American States Financial Corporation	97–2724	07/15/97
Commercial Union plc, Charter Oak Partners, York Holding Company	97–2729	07/15/97
Cheryl L. Thompson, Watson Electric Supply Company, Watson Electric Supply Company	97–2733	07/15/97
Bindley Western Industries, Inc., James E. Richards, Tennessee Wholesale Drug Company, Inc.	97–2735	07/15/97
MasTec, Inc., Wilde Construction, Inc., Wilde Construction, Inc	97–2737	07/15/97
Ronald A. Weinberg/Micheline Charest, Stephen T. Carson & Patricia L. Carson, Carson-Dellosa Publishing Company, Inc.; The Wild Goose	97–2738	07/15/97
Torstar Corporation (a Canadian company), Mr. Jarret Schecter, Troll Communications, LLC	97–2739	07/15/97
CRH plc, Lone Star Industries, Inc., New York Trap Rock Corporation	97–2742	07/15/97
Harrowston, Inc., Anchor Lamina Inc., Anchor Lamina Inc	97–2619	07/16/97
Genesis Health Ventures, Inc., Genesis ElderCare Corp., Genesis ElderCare Corp	97–2642	07/16/97
TPG Partners II, L.P., Genesis ElderCare Corp., Genesis ElderCare Corp	97–2643	07/16/97
Genesis Health Ventures, Inc., Genesis ElderCare Corp., The Multicare Companies	97–2645	07/16/97
TPG Investors II, L.P., Genesis ElderCare Corporation, Genesis ElderCare Corporation	97–2653	07/16/97
Edward K. Mullen, Daniel J. Sparler, Yorktowne Paper Mills, Inc.; Yorktowne Paper Mills of	97–2676	07/16/97
Apollo Investment Fund III, L.P., Three Rivers Holding Corporation, Three Rivers Holding Corporation	97–2703	07/16/97
Cox Enterprises, Inc., H and P Radio, WBHJ, L.L.C., an Alabama Limited liability Company	97–2736	07/16/97
Cypress Merchant Banking Partners, L.P., Genesis ElderCare Corp., Genesis ElderCare Corp	97–2644	07/17/97
USA Waste Services, Inc., David R. Kraemer, Edward Kraemer & Sons, Inc	97–1887	07/18/97
Clear Channel Communications, Inc., Triathlon Broadcasting Company, Triathlon Broadcasting of Little Rock, Inc	97–2126	07/18/97
AlliedSignal Inc., Grimes Partnership, L.P., FL Aerospace Holdings Corp	97–2564	07/18/97
Intellicall, Inc., WorldCom, Inc., WorldCom, Inc	97–2616	07/18/97
Cole National Corporation, Michael J. Rosenthal, American Vision Centers, Inc	97–2635	07/18/97
Cole National Corporation, The Fuji Bank, Limited, American Vision Centers, Inc	97–2636	07/18/97
Wolters Kluwer, nv, The Walt Disney Company, NILS Holding Company, Inc	97–2750	07/18/97
Key Energy Group, Inc., Nabors Industries, Inc., J.W. Gibson Well Service Company	97–2755	07/18/97
ACX Technologies, Inc., Tetrafluor, Inc., Tetrafluor, Inc	97–2759	07/18/97
Reinhold Wurth, Winston L. Adams, Adams Nut and Bolt Co	97–2760	07/18/97
NationsBank Corporation, Michael Weintraub, Gibson Security Corp	97–2761	07/18/97
Kenneth R. Thomson, Journal Printing Company of Stevens Point, Wisconsin, Journal Printing Company of Stevens Point, Wisconsin	97–2762	07/18/97
Carrols Holdings Corporation, Richard D. Fors, Jr., see attached list	97–2765	07/18/97
ERGON, Inc., Quaker State Corporation, Quaker State Corporation	97–2767	07/18/97
Metal Management, Inc., Albert A. Cozzi, Cozzi Iron & Metal, Inc	97–2769	07/18/97
Albert A. Cozzi, Metal Management, Inc., Metal Management, Inc	97–2770	07/18/97
Frank J. Cozzi, Metal Management, Inc., Cozzi Iron & Metal, Inc	97–2771	07/18/97
Argotyche, LP, Veda International Inc., Veda International Inc	97–2776	07/18/97
Hallmark Cards, Inc. Voting Trust dated 12/04/68, William A. DeJonge, William Arthur, Inc	97–2777	07/18/97
Cook Inlet Region, Inc, Harry DeNardi, DeNardi Corporation; DeNardi Equipment Company	97–2779	07/18/97
Lehman Brothers Holdings Inc., Harbourton Holdings, L.P., Harbourton Mortgage Co., L.P	97–2780	07/18/97
Atlas Copco AB (jointly with) Prime Service, Inc., Robert Shanin, Norquip Rentals Corpor- ation/Assets	97–2785	07/18/97
Lawrence J. Ellison, SuperGen, Inc., SuperGen, Inc	97–2786	07/18/97
Whitney Equity Partners, L.P. , Lyonnaise des Eaux, Aqua-Chem. Inc	97–2787	07/18/97
Bruckmann, Rosser, Sherrill & Co., L.P., PepsiCo, Inc., California Pizza Kitchen, Inc	97–2788	07/18/97
American Radio Systems Corporation, Amaturo Group of California, Ltd., Amaturo Group of California, Ltd	97–2794	07/18/97
A. Ahlstrom Corporation, H. Lynden Graham, Trustee for American Fiber Resources, American Fiber Resources, L.P	97–2815	07/18/97

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, D.C. 20580, (202) 326–3100.

By Direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–19898 Filed 7–28–97; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[Docket No. 9280]

Blue Coral, Inc.; Blue Coral-Slick 50, Inc.; Blue Coral-Slick 50, Ltd.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft amended complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before September 29, 1997.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Elaine D. Kolish, Federal Trade Commission, S–4302, 6th & Pennsylvania Ave., NW., Washington, DC 20580. (202) 326–3042. Mary K. Engle, Federal Trade Commission, S–

4302, 6th & Pennsylvania Ave., NW., Washington, DC 20580; (202) 326–3161.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and Section 3.25 of the Commission's Rules of Practice (16 CFR 3.25), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the accompanying complaint. An electronic copy of the full text of the consent agreement package can be obtained from the Commission Actions section of the FTC Home Page (for July 24, 1997), on the World Wide Web, at ''http://www.ftc.gov/os/actions/htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, Sixth Street and Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Blue Coral, Inc.; Blue Coral-Slick 50, Inc.; and Blue Coral-Slick 50, Ltd. These three entities are successors in interest to Quaker State—Slick 50, Inc.; Slick 50 Management, Inc.; Slick 50 Products Corp.; and Slick 50 Corp. (all entities collectively, ''respondents'').

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves allegedly deceptive representations for Slick 50 engine treatment, and aftermarket motor oil additive containing particles of the polymer polytetrafluoroethylene (''PTFE''). The Commission issued a complaint on July 12, 1996, charging that advertisements for Slick 50 disseminated by the respondents made various false and unsubstantiated claims. The Commission's complaint was withdrawn from adjudication on May 12, 1997, prior to commencement of the administrative hearing, so that the Commission could consider the proposed order.

According to the FTC complaint, the respondents falsely claimed: (1) Automobile engines generally have little or no protection from wear at or just after start-up unless they have been treated with Slick 50; (2) Automobile engines commonly experience premature failure caused by wear unless they are treated with Slick 50; (3) Slick 50 coats engine parts with a layer of PTFE; and (4) Slick 50 meets military specifications for aftermarket motor oil additives. The complaint alleged the following claims as unsubstantiated: (1) Compared to motor oil alone, Slick 50: reduces engine wear, reduces engine wear by more than 50%, reduces engine wear by up to 50%, reduces engine wear at start-up, extends the duration of engine life, lowers engine temperatures, reduces toxic emissions, increases gas mileage, and increases horsepower; (2) One treatment of Slick 50 continues to reduce engine wear for 50,000 miles; and (3) Slick 50 has been used in a significant number of U.S. Government vehicles. Lastly, the complaint alleged that respondents falsely represented: (1) Tests prove that, compared to motor oil alone, Slick 50: reduces engine wear by more than 50%, reduces engine wear by up to 50%, and reduces engine wear at start-up; and (2) Tests prove that one treatment of Slick 50 continues to reduce engine wear for 50,000 miles.

The proposed consent order contains provisions designed to prevent the respondents from engaging in similar acts and practices in the future. Part I of the proposed order prohibits the respondents from representing that: (1) Automobile engines generally have little or no protection from wear at or just after start-up unless they have been treated with Slick 50 or a similar PTFE product; (2) Automobile engines commonly experience premature failure caused by wear unless they are treated with Slick 50 or a similar PTFE product; or (3) Slick 50 or a similar PTFE product coats engine parts with a layer of PTFE.

Part II of the proposed order prohibits the respondents from misrepresenting that any oil additive or Slick 50 engine lubricating product meets the standards of any organization and from misrepresenting tests or studies when selling such products. Part II also prohibits the respondents from making any representation about the performance, benefits, efficacy, attributes or use of such products unless, at the time they make the representation, they possess and rely upon appropriate, competent and reliable evidence that substantiates the representation.

Part III of the proposed order prohibits respondents from representing that any Slick 50 lubricating product for use in a motor vehicle, other than an engine lubricating product, reduces wear, extends the life of a part, lowers engine temperature, reduces emissions, or increases mileage or horsepower, unless, at the time they make the representation, they possess and rely upon appropriate, competent and reliable evidence that substantiates the representation.

Parts IV through IX and XI require the respondents to keep copies of advertisements making representations covered by the order; to keep records concerning those representations; including materials that they relied upon when making the representations, to notify the Commission of changes in corporate structure; to provide copies of the order to certain of respondents' personnel; to send notice of the order to purchasers for resale of Slick 50; to keep records showing that the order or notice of the order was received by or sent to appropriate persons and showing any redress made available to consumers pursuant to class action lawsuits challenging conduct similar to that challenged in the Commission's complaint; to provide notice to Commission staff prior to submitting any proposed settlement of such class action lawsuits to a court; and to file with the Commission compliance reports and reports showing any redress made available to consumers pursuant to class action lawsuits. Part X provides that the order will terminate after twenty (20) years under certain circumstances.

Additionally, Paragraph 5 of the consent agreement seeks to preserve the Commission's option to seek consumer redress under Section 19 of the Federal Trade Commission Act if the respondents do not make available redress having an aggregate retail value of at least $10 million to consumers pursuant to class action lawsuits that challenge conduct similar to that challenged in the Commission's complaint. Paragraph 5 also reserves the Commission's right to seek to intervene in any such class action lawsuit to oppose a settlement that it believes is not in the public interest.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of

the agreement and proposed order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–19897 Filed 7–28–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science; Federal Policies Affecting the Future of Academic Health Centers

AGENCY: Office of Public Health and Science.

ACTION: Notice of two public hearings, and comment.

SUMMARY: This notice announces that the Secretary of Health and Human Services is formally inviting public comment on issues relevant to the Department's Initiative on the Future of Academic Health Centers. The Secretary has established an interagency policy development group to review Department policies affecting academic health centers and other health professions work force issues. The policy development group will make recommendations to the Secretary for revising or implementing Federal policies that ensure that the essential public goods produced by academic health centers are maintained in the evolving health care system. These essential public goods (health professions education, biomedical and other health research, and services to vulnerable or disadvantaged individuals, as well as special services, i.e., trauma care, burn units, and transplantation units), are critical to the nation's health care system.

The policy development group of the Department's initiative is interested in gaining local and regional perspectives from across the country on the issues that surround the future of academic health centers. To gain this input, two national public hearings will be held. These hearings will focus on issues related to the future of education and research missions of academic health centers, the provision of services through academic health centers, and academic health centers' need for access to capital to achieve these missions. Individuals may provide oral comments regarding the future of academic health centers, and Federal policies affecting them. The testimony provided by key stakeholders/constituents will be considered in the development of recommendations to the Secretary. Written comments will also be accepted.

DATES: Two public hearings will be held: August 25, 1997 in Houston, TX and August 27, 1997 in Chicago, IL. Requests to give oral testimony at the hearings must be received in writing by August 7, 1997. Written comments accompanying oral testimony are due August 11, 1997 for the August 25, 1997 hearing and on August 13, 1997 for the August 27, 1997 hearing. Submission deadline for written comments, without oral testimony, is August 23, 1997.

ADDRESSES: Written requests to testify and written comments on Federal policies that impact the future of academic health centers should be submitted to: Ciro V. Sumaya, M.D., M.P.H.T.M., Deputy Assistant Secretary for Health, Department of Health and Human Services, Hubert H. Humphrey Building, Room 716–G, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: The office of Dr. Sumaya at the address listed above. Telephone: (202) 690–7694. Facsimile: (202) 260–4405. Electronic mail: AHCInitiative@osophs.dhhs.gov

SUPPLEMENTARY INFORMATION:

Location Information

Sammons Auditorium, Texas Medical Center Library, 1133 M.D. Anderson Boulevard, Houston, Texas, 77030 on August 25, 1997, 8:30 AM. Dirksen Building, 219 S. Dearborne Street, Courtroom #2541, Chicago, Illinois, 60604, on August 27, 1997, 8:30 AM.

Guidelines for Submitted Testimony

Those wishing to present written testimony only should accompany their testimony with an abstract that summarizes their testimony in 200 words or less.

Those wishing to present oral testimony should indicate the following in their requests: (1) which of the two public forums (Houston, Texas, August 25, 1997, or Chicago, Illinois, August 27, 1997) they would like to attend depending upon availability; (2) the type of institution or organization they represent (academic health center or school, professional association, community organization, state/local government, foundation, health plan, insurer, other provider, or other), and their mailing address, telephone number, facsimile number, and electronic mail address (if available). Written comments may be longer than the oral testimony presented. An abstract that summarizes the testimony, in 200 words or less, must accompany the written testimony.

Both of these hearings will be limited one day; therefore, it is possible that all those who wish to present oral testimony may not be accommodated. Requests for oral presentations will be honored on a first come, first serve basis. Opportunity will be provided for representation by a variety of stakeholders/constituencies, as identified above, as well as to ensure geographic distribution. Oral comments must be limited to no more than five minutes. Presenters will be notified by telephone if they will have the opportunity to provide oral testimony, with a follow-up confirmation in writing.

Testimony Content Guidelines

Both public hearings will address issues related to academic health centers' education and research missions and the provision of health care services (to under served populations, and specialized services), and related needs for access to capital to support these public missions.

Written and oral testimony prepared for these public hearings should address one or more of these questions:

Education/Work Force

What role should academic health centers play in developing the nation's health professions work force? What are the current threats and barriers to achieving those educational roles and accompanying goals?

What Federal policies are needed to improve academic health centers' capacity to produce an appropriate health professions work force at the regional, state, and national level?

Is the use of consortia (e.g., hospital networks, health professions schools) an effective means to improve health professions training and education? Are there other models? Are specific demonstrations and projects useful?

Research

What is the current status of the nation's health research enterprise (i.e., biomedical, clinical, behavioral, health services, prevention/population based research)?

What are some strategies for maintaining a strong and productive research infrastructure, including training programs, support services, and physical plants and operations?

What policies are needed to maintain and improve the nation's health research capacity and productivity?

Services

Are services to vulnerable and under served populations traditionally provided by academic health centers at

risk due to recent changes in health care delivery and financing? If so, how are academic health centers addressing these?

What Federal policy changes, if any, are needed to assist academic health centers in providing quality health services to vulnerable and under served populations?

How are the special services (e.g., burn units, trauma Centers, organ transplantation programs, etc.) that are frequently, if not primarily, performed at academic health centers being affected by the changing health care environment? If these special services are being adversely affected, how are academic health centers addressing this? Can/should Federal policy assist these institutions?

Access to Capital

What are the capital needs of academic health centers? Do academic health centers have access to adequate capital resources to support the education, research and service mission of academic health centers?

Are the Federal policies that influence access to capital resources appropriate? If not, what Federal policy changes are needed to facilitate academic health centers' access to capital?

DHHS Initiative on Academic Health Centers

Description of Academic Health Centers

Academic health centers are major complexes comprised of a school of medicine, at least one other health professions school (nursing, dentistry, allied health, public health, pharmacy, etc.) and one or more teaching hospitals. There are over 100 academic health centers in the United States, more than 75 percent having three or more health professions schools. These centers may be components of private or public universities or State university systems, or they can be freestanding institutions.

Mission of Academic Health Centers

Academic health centers are an integral part of the American health care system. These centers produce valuable public goods for the country, including 40 percent of the health research and development and thirty three percent of the highly specialized, complex care for patients with major trauma as injuries or burns, AIDS, and other intensive care. They are a principal resource for the training and education of the future health care professional workforce. Academic health centers—especially publicly owned ones—provide over one third of the nation's uncompensated (charity and bad debt) health care.

Challenges Facing Academic Health Centers

Many changes in the evolving health care environment, including the rapid expansion of managed care, are posing a number of serious challenges for these centers and the health professions workforce. These challenges include fiscal survival and stability in a competitive health care marketplace, diminished subsides for the academic mission in research and education, urgent demand to develop a strong capacity in primary (general) care and training of future health professionals in ambulatory (non-hospital) settings, information technology needs that are quite expensive, and external pressures for increased accountability as a public goods resource.

Stakeholder of Academic Health Centers

Academic health centers are linked to a variety of entities such as universities, local-State-Federal government agencies, managed care organizations, health insurance industry, pharmaceutical companies, telecommunications companies and the general business community, among many others. Moreover, these centers are closely tied to the health and economy of the communities they serve.

Federal Government Partnership

DHHS oversees numerous programs that directly or indirectly provide financial, physical, human, and technical resources to the academic health center enterprise. These resources support graduate medical education and other health professions training and education, biomedical and other health research, institutional and student loan programs, and services to Medicare and Medicaid participants. The Veteran's Administration and the Department of Defense are additional components of the Federal government than help support academic health centers.

DHHS Initiative

This initiative was established to update and develop relevant policy at the Federal level that can ensure the academic health centers' capacity to achieve their public good mission in a new, evolving health care system. DHHS Secretary Shalala has appointed Dr. Ciro Sumaya, Deputy Assistant Secretary for Health, to lead an interagency policy development task force focusing on the future of the centers. The task force will also work with the Departments of Veterans Affairs and Defense, State governments, the academic community, and other public and private sectors partners in this process. Recommendations on policy options and actions are to be submitted to the Secretary by the end of September 1997. The recommendations will address the current development of the health professions work force as well as financial, research, and service infrastructure issues facing academic health centers.

Dated: July 23, 1997.

John M. Eisenberg,

Acting Assistant Secretary for Health.

[FR Doc. 97–19982 Filed 7–25–97; 12:24 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meeting

AGENCY: Office of Disease Prevention and Health Promotion, HHS.

ACTION: Commission of dietary supplement labels: notice of meeting #9.

SUMMARY: The Department of Health and Human Services (HHS) is providing notice of the ninth meeting of the Commission on dietary supplement labels.

DATES: The Commission intends to hold its meeting on August 14, 1997, from 8:30 a.m. to 4:30 p.m. and on August 15, 1997, from 8:30 a.m. to approximately 3:00 p.m., E.S.T., at the Hyatt Regency Reston, Reston Town Center, 1800 Presidents Street, Reston, Virginia 20190. The meeting is open to the public; seating is limited.

FOR FURTHER INFORMATION CONTACT: Kenneth D. Fisher, Ph. D., Executive Director, Commission on Dietary Supplement Labels, Office of Disease Prevention and Health Promotion, Room 738G, Hubert H. Humphrey Building, 200 Independence Ave. S.W., Washington, D.C. 20201, (202) 690–7102.

SUPPLEMENTARY INFORMATION: Pub. L. 103–417, Section 12, authorized the establishment of a Commission on Dietary Supplement Labels whose seven members have been appointed by the President. The appointments to the Commission by the President and the establishment of the Commission by the Secretary of Health and Human Services reflect the commitment of the President and the Secretary to the development of a sound and consistent regulatory policy on labeling of dietary supplements.

The Commission is charged with conducting a study and providing recommendations for regulation of label claims and statements for dietary supplements, including the use of

supplemental literature in connection with their sale and, in addition, procedures for evaluation of label claims. The Commission is evaluating how best to provide truthful, scientifically valid, and non-misleading information to consumers in order that they may make informed health care choices for themselves and their families. The Commission's study report may include recommendations on legislation, if appropriate and necessary.

The Commission made a draft of its report available for public comment on June 24, 1997. The purpose of meeting #9 is to review comments and information received from the public and to discuss preparation of the Commission's final report.

The Commission meeting agenda will include approval of minutes of the previous meeting, review of comments and information submitted by the public, and discussion of possible revisions of the draft report and procedures for final report completion. The open meeting may be recessed for short time periods on Thursday afternoon, August 14, 1997, and on Friday morning, August 15, 1997, at the call of the Chair, to allow members of the Commission to redraft portions of the report. Following such recesses, if any, the revisions will be presented to the full Commission in its open meeting.

The meeting is open to the public, however seating is limited. If you will require a sign language interpreter, please call Sandra Saunders (202) 690–7102 by 4:30 p.m. E.S.T. on August 4, 1997.

Dated: July 17, 1997.

Susanne A. Stoiber,

Acting Deputy Assistant Secretary for Health, (Disease Prevention and Health Promotion), U.S. Department of Health and Human Services.

[FR Doc. 97–19909 Filed 7–28–97; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–16–97]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 7 days of this notice.

Proposed Project

1. The National Home and Hospice Care Mail Survey (NHHCMS)—(0920–0298)—Revision—The National Center for Health Statistics (NCHS) is requesting an emergency review and clearance of the above named data collection in 1997. The use of the regular clearance process for this survey would preclude collection of home health care data in 1997, thereby disrupting the provisions of annual trend data for this dynamic sector in the health care delivery system. A decision regarding this request is needed by August 8, 1997. The National Home and Hospice Care Survey was conducted in 1992, 1993, 1994 and 1996. It is part of the Long-Term Care component of the National Health Care Survey. Section 306 of the Public Health Service Act states that the National Center for Health Statistics ''shall collect statistics on health resources * * * (and) utilization of health care, including utilization of * * * services of hospitals, extended care facilities, home health agencies, and other institutions.'' NCHS data are used to examine this most rapidly expanding sector of the health care industry. Data from the NHHCS are widely used by the health care industry and policy makers for such diverse analyses as the need for various medical supplies; minority access to health care; and planning for the health care needs of the elderly. The NHHCS also reveals detailed information on utilization patterns, as needed to make accurate assessments of the need for and costs associated with such care. Data from earlier NHHCS collections have been used by the Congressional Budget Office, the Bureau of Health Professions, the Maryland Health Resources Planning Commission, the National Association for Home Care, and by several newspapers and journals.

Additional uses are expected to be similar to the uses of the National Nursing Home Survey. The mail survey version is an abbreviated form used to collect basic trend data in years in which the full NHHCS is not in the field. NHHCMS data cover: baseline data on the characteristics of home health agencies and hospices including number of patients served, ownership, Medicare and Medicaid certification, and services provided. Data collection is planned for the period October 1997–January 1998. Survey design is in process now. The total annual burden hours are 200.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/response (in hours)
Hospices and Home Health Care Agencies	1,200	1	0.166

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–19892 Filed 7–28–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–17–97]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

1. National Surveillance System for Hospital Health Care workers (NASH)—New—CDC has developed a surveillance system that focuses on surveillance of exposures and infections among hospital-based health care workers (HCWs). This system, modeled after the National Nosocomial Infections Surveillance (NNIS) system for patient infections, includes standardized methodology for various occupational health issues (OMB 0920–0012). The Hospital Infections Program, National Center for Infectious Diseases (NCID) has developed this system in collaboration with the Hepatitis Branch, Division of Viral and Rickettsial Diseases, NCID; the Division of Tuberculosis (TB) Elimination, National Center for HIV, STD, and TB Prevention; the National Immunization Program (NIP), and the National Institute for Occupational Safety and Health (NIOSH).

The NASH system consists of modules for collection of data about various occupational issues. Baseline information about each HCW such as demographics, immune-status for vaccine-preventable diseases, and TB status is collected when the HCW is enrolled in the system. Results of routine tuberculin skin test (TST) are collected and entered in the system every time a TST is placed and read. In the event that an HCW is exposed to blood/bloodborne pathogen, to a vaccine-preventable disease, or to a TB infectious patient/HCW, epidemiologic data will be collected about the exposure. For HCWs exposed to a bloodborne pathogen (i.e., HIV, HCV, or HBC), follow-up data will be collected during the follow-up visits. Once a year, the hospitals will perform a survey to assess the level of under reporting of needlesticks (HCW Survey) and will complete a hospital survey to provide denominator data. Data will be sent entered into the software and diskettes will be sent to CDC. No identifiers of the HCW will be sent to CDC. This system is protected by the Assurance of Confidentiality (308d).

Data collected in this surveillance system will assist hospitals, HCWs, HCW organizations, and public health agencies. This system will allow CDC to monitor national trends, to identify newly emerging hazards for HCWs, to assess the risk of occupational infection, and to evaluate preventive measures, including engineering controls, work practices, protective equipment, and postexposure prophylaxis to prevent occupationally acquired infections. Hospitals who volunteer to participate in this system will benefit by receiving technical support and standardized methodologies, including software, for conducting surveillance activities on occupational health.

This system has been developed and piloted in large teaching hospitals. Prior to implementation in a nationwide network of hospitals, an expansion of this pilot project to include more medium/small size hospitals is essential for further refinement of protocols and software. The first pilot project ran from October 1994 to September 1996 (RFP–200–94–0834(P)) and included four hospitals; the second pilot started in October 1996 (RFP–200–96–0524(P)) and includes five hospitals. Fifteen hospitals are expected to participate in this proposed project, including the five currently participating. Once the expanded pilot project is completed, the system will be made available to all short-term care hospitals in the United States who wish to voluntarily participate in this project. The total annual burden hours are 14,554.

Respondents	Number of respondents	Number of responses/ respondents	Average burden/response (in hours)
Baseline Information Form	15	1,500	0.3333
TST—Result Form	15	1,500	0.1666
TST—Evaluation Form	15	13	0.1666
Exposure to Blood Form	15	100	0.4166
Exposure to Blood Follow-up Form	15	50	0.25
Exposure to vaccine-prv. dis—Summary Form	15	8	0.3333
Exposure to vaccine-prv. dis—HCW Form	15	16	0.3333
Exposure to TB Form	15	3	0.50
Exposure to Non-Infectious Injury Form	15	133	0.3333
Exposures to Blood During Surgery Form	15	80	0.1666
Exposures to Blood During OB Deliveries Form	15	80	0.1666
HCW Survey	15	500	0.1666

* The same 15 hospitals will be completing the 12 separate forms listed above. The number of respondents includes x number of employees times each of 15 hospitals.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–19893 Filed 7–28–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0453]

Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation.'' The purpose of the guidance document is to assist facilities involved in recovery, infectious disease testing, screening, processing, storing, or distributing human tissue intended for transplantation. The guidance document provides information on procedures and practices for donor screening and testing. FDA prepared the guidance document after receiving public input. The topics included in the guidance document were contained in a draft document ''Screening and Testing of Donors of Human Tissue Intended for Transplantation'' made available for discussion at a public workshop on human tissue held on June 20 and 21, 1995.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the ''Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844.

Persons with access to the Internet may obtain the document using File Transfer Protocol (FTP), the World Wide Web (WWW), or bounce–back e–mail. For FTP access, connect to CBER at ''ftp://ftp.fda.gov/cber/''. For WWW access, connect to CBER at ''http://www.fda.gov/cber/publications.htm''. To receive the document by bounce–back e–mail, send a message to ''tissue2@a1.cber.fda.gov''.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except individuals may submit one copy. Requests and comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 14, 1993 (58 FR 65514), FDA published an interim rule on human tissue intended for transplantation to reduce the risk of transmission of human immunodeficiency virus (HIV) and hepatitis through human tissue intended for transplantation. The interim rule was issued under the authority of sections 215, 311, 361, and 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271) because of an immediate need to protect the public health from the transmission of communicable diseases through the transplantation of human tissue. The interim rule established requirements for the testing of donors of human tissue for HIV Type 1 virus, HIV Type 2 virus, hepatitis B virus, and hepatitis C virus. The interim rule also required that donors be screened for medical history, including behaviors that carry an increased risk of exposure to these viruses (behavioral and high risk information) and for signs and symptoms of infection with these viruses.

In the **Federal Register** of June 20, 1995 (60 FR 32128), FDA announced the availability for public comment of a draft document entitled ''Screening and Testing of Donors of Human Tissue Intended for Transplantation.'' The availability of the draft document coincided with the workshop on Human Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives which was held on June 20 and 21, 1995. Comments received on this draft document and the issues discussed at the workshop were considered in the development of the guidance document being announced in this notice.

This guidance document provides general information on the following procedures: (1) Determination of donor suitability, (2) evaluation of screening test performance, (3) application of a plasma dilution algorithm to determine the acceptability of the blood specimen used for testing, (4) screening for behavioral and high risk information, and (5) evaluation of clinical and physical evidence of infection with HIV or hepatitis.

As technical standards change over time due to an increased understanding of infectious diseases and improved technology for testing, FDA may issue future guidance to help ensure that the regulatory process reflects the current level of knowledge. The recommendations in this guidance document should be considered in addition to voluntary standards developed and used by human tissue organizations.

This document is not being issued under the authority of 21 CFR 10.90(b) because FDA is in the process of revising this section. As with other guidance documents, FDA does not intend this document to be all–inclusive. This document does not bind the agency and does not create or confer any rights, privileges, or benefits for or on any person. Tissue facilities may follow the guidance document or may choose to use alternative procedures not provided in the guidance document. If a tissue facility chooses to use alternative procedures, the facility may wish to discuss the matter further with the agency to prevent expenditure of resources on activities that may be unacceptable to FDA.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Continued comment by the human tissue industry is encouraged, and comments will be continuously accepted by the Dockets Management Branch.

FDA periodically will review written comments on the guidance document to

determine whether future revisions to the guidance document are warranted.

Dated: January 21, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–19821 Filed 7-28-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–P–15A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey (MCBS) Rounds: 20–32; *Form No.:* HCFA–P–15A (OMB# 0938–0568); *Use:* The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons enrolled in Medicare. The survey provides a comprehensive source of information on beneficiary characteristics, needs, utilization, and satisfaction with Medicare-related activities; *Frequency:* Other (3 times a year per respondent); *Affected Public:* Individuals and households; *Number of Respondents:* 16,000; *Total Annual Responses:* 48,000; *Total Annual Hours:* 48,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 9, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97–19924 Filed 7–28–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Genetic Epidemiology of Lung Cancer I and II.

Date: August 4, 1997.

Time: 11:00 a.m. to 12:30 p.m.

Place: Teleconference, National Cancer Institute, Executive Plaza North, Room 635G, 6130, Executive Boulevard, Bethesda, MD 20892.

Contact Person: Sally A. Mulhern, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 635G, 6130 Executive Boulevard, MSC 7410, Bethesda, MD 20892–7410, Telephone: 301/496–7413.

Purpose/Agenda: To evaluate and review grant applications.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: July 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–19848 Filed 7–28–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Cancer Institute Special Emphasis Panel (SEP) meetings:

Name of SEP: Pivotal Clinical Trials for Chemoprevention Agent Development.

Date: August 18–19, 1997.

Time: August 18—7:00 a.m.–5:00 p.m.; August 19—8:00 a.m.–5:00 p.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, Md 20852.

Contact Person: Ray Bramhall, PhD., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 636, 6130 Executive Boulevard, MSC 7410, Bethesda, Md 20892–7410, Telephone: 301/496–3428.

Purpose/Agenda: To evaluate and review grant applications.

Name of SEP: Chemoprevention in Genetically-Identified High-Risk Groups: Interactive Research and Development Project.

Date: August 25–26, 1997.

Time: August 25—8:30 a.m.–5:00 p.m.; August 26—8:00 a.m.–5:00 p.m.

Place: Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, Md 20814.

Contact Person: Ray Bramhall, PhD., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 636, 6130 Executive Boulevard, MSC 7410, Bethesda, Md 20892–7410, Telephone: 301/496–3428.

Purpose/Agenda: To evaluate and review grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commerical property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395,

Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: July 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–19854 Filed 7–28–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: NIH–AIDS Research and Reference Reagent Program.

Date: August 5, 1997.

Time: 10:00 a.m. to Adjournment.

Place: Teleconference, 6003 Executive Boulevard, Solar Building, Room 1A04, (301) 496–4640.

Contact Person: Ms. Janet R. Terner, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C02, Bethesda, MD 20892, (301) 496–2550.

Purpose/Agenda: To evaluate contract proposals.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated July 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–19849 Filed 7–28–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel meetings:

Name of SEP: Molecular Dynamics of Iron Regulation & Function.

Date: August 18–20, 1997.

Time: 7:30 pm.

Place: University Place Hotel and Conference Center, 850 W. Michigan Street, Indianapolis, Indiana 46202–2800.

Contact Person: Lakshmanan Sankaran, Ph.D., Scientific Review Administrator, Review Branch, NIDDK, Natcher Building, Room 6as–25F, National Institutes of Health, Bethesda, Maryland 20892–6600, Phone: (301) 594–7799.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Tools for Discovery of Anti-Osteoporotic Drugs.

Date: August 26, 1997.

Time: 2:00 pm.

Place: Room 6as–25E, Natcher Building, NIH (Telephone Conference Call).

Contact Person: Sharee Pepper, Ph.D., Scientific Review Administrator, Review Branch, NIDDK, Natcher Building, Room 6as–25E, National Institute of Health, Bethesda, Maryland 20892–6600, Phone: (301) 594–7798.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.847–849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: July 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–19850 Filed 7–28–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: August 1, 1997.

Time: 2 p.m.

Place: Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, Md 20857.

Contact Person: Sheri L. Schwartzback, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, Md 20857, Telephone: 301, 443–4843.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: August 7–August 9, 1997.

Time: 8 a.m.

Place: Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, Md 20857.

Contact Person: Jean G. Noronha, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, Md 20857, Telephone: 301, 443–6470.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: July 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–19851 Filed 7–28–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Purusant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following

National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: Studies of HIV in Women Under the Women's Interagency HIV Study.
Date: September 10–11, 1997.
Time: 8:30 a.m. to Adjournment.
Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814, (301) 652–2000.
Contact Person: Dr. Peter R. Jackson, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C10, Bethesda, MD 20892, (301) 496–2550.
Purpose/Agenda: To evaluate grant applications.

Name of SEP: Women's Interagency HIV Study Date Management and Analysis Center.
Date: September 11–12, 1997.
Time: 1:30 p.m. to Adjournment.
Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814, (301) 652–2000.
Contact Person: Dr. Peter R. Jackson, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C10, Bethesda, MD 20892, (301) 496–2550.
Purpose/Agenda: To evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: July 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–19852 Filed 7–28–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting: AIDS Research Advisory Committee, NIAID

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the AIDS Research Advisory Committee, National Institute of Allergy and Infectious Diseases, on September 9, 1997 in Conference Room E1 and E2, Natcher Conference Center, Building 45, at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland.

The entire meeting will be open to the public from 8:30 a.m. until adjournment. The AIDS Research Advisory Committee (ARAC) advises and makes recommendations to the Director, National Institute of Allergy and Infectious Diseases, on all aspects of research on HIV and AIDS related to the mission of the Division of AIDS (DAIDS).

The Committee will provide advice on scientific priorities, policy, and program balance at the Division level. The Committee will review the progress and productivity of ongoing efforts, and identify critical gaps/obstacles to progress. Attendance by the public will be limited to space available.

Ms. Rona L. Siskind, Executive Secretary, AIDS Research Advisory Committee, DAIDS, NIAID, NIH, Solar Building, Room 2A21, telephone 301–435–3732, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Siskind in advance of the meeting.

(Catalog of Federal Domestic Assistance Program Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: July 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–19853 Filed 7–28–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–040–07–1310–00]

Notice of Availability of Draft Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability of Draft Environmental Impact Statement.

SUMMARY: The Bureau of Land Management announces the availability of the Jonah Field II Natural Gas Development Project (Jonah Field) Draft Environmental Impact Statement (DEIS) which analyzes the environmental consequences of the Jonah Field proposed natural gas development and production operation. The Jonah Field project area is approximately 32 miles south of Pinedale, Wyoming, and 28 miles north of Farson, Wyoming, and located within portions of Townships 28 and 29 North, Ranges 107, 108, and 109 West, Sixth Principal Meridian, Sublette County, Wyoming. The project area encompasses a potential natural gas field of up to 59,600 acres, where 49 wells are presently active or have been previously analyzed, and where up to 450 additional wells could be drilled over the next 15 years.

DATES: Comments on the DEIS will be accepted for 45 days following the date that the Environmental Protection Agency (EPA) publishes their notice of availability in the **Federal Register**. The EPA notice is expected to be published on July 25, 1997.

ADDRESSES: Comments on the DEIS should be sent to Bureau of Land Management, Arlan Hiner, Team Leader, 280 Highway 191 North, Rock Springs, WY 82901.

SUPPLEMENTARY INFORMATION: McMurry Oil Company, Snyder Oil Corporation, Amoco Production Co., and Western Gas Resources, Inc. (Operators) propose to explore and develop their existing leases within the Jonah Field project area. The Operators propose to expand the Jonah Field from 49 current wells by drilling up to 450 additional wells over the next 15 years. The wells would be drilled on 80-acre spacing (i.e., a well density of eight wells per 640 acres). The Operators' plans and drilling schedules would be contingent upon an adequate price for the gas at the wellhead.

The Jonah Field DEIS analyzes the impacts of the Proposed Action, a Sensitive Resource Protection Alternative, a Maximum Density of 4 Well Locations/Section, and the No Action Alternative. Based on the issues and concerns identified during the scoping process, the DEIS focuses on the impacts to socio-economics, wildlife, air quality, land use, and cumulative effects. Key issues include effects upon people and communities near the project area and the State as a whole; effects to antelope and antelope habitat, sage grouse and raptor breeding and nesting; potential reductions in air quality and visibility; potential reductions in water quality; impacts for surface disturbance; and transportation planning.

The DEIS, in compliance with Section 7(c) of the Endangered Species Act (as amended), includes the Biological Assessment for the purpose of identifying endangered or threatened species which may be affected by the proposed action.

Comments, including names and street addresses of respondents, will be available for public review at the address listed above during regular

business hours (7:45 a.m.–4:30 p.m.), Monday through Friday, except holidays, and may be published as part of the DEIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

Dated: July 16, 1997.

Alan L. Kesterke,

Associate State Director.

[FR Doc. 97–19845 Filed 7–28–97; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–018–1220–00/G010–G7–0253]

Amendment to a Notice of Availability of a Draft Coordinated Resource Management Plan (CRMP) and Environmental Impact Statement (EIS); Taos Resource Area, New Mexico and San Luis Resource Area, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Amendment to notice.

SUMMARY: The Bureau of Land Management (BLM) Albuquerque District, Taos Resource Area and Cañon City District, San Luis Resource Area have completed a Draft CRMP/EIS, and a Taos Resource Management Plan Amendment. This notice amends the Notice of Availability printed in the **Federal Register** on Friday, June 27, 1997 (Vol. 62, No. 124, 34771–72), adding a fourth public hearing in response to public interest, and extending the public comment period through October 20, 1997, to meet Environmental Protection Agency requirements.

DATES: Written comments must be postmarked no later than October 20, 1997, and should be addressed to the CRMP Team Leader at the address below. Inaddition to the hearings announced in the June 27 Notice of Availability, formal oral comments will be received at the following public hearing, beginning at 7 p.m.: September 3, 1997—Dixon Elementary Gymnasium, State Road 75, Dixon, New Mexico.

FOR FURTHER INFORMATION CONTACT: CRMP Team Leader, Taos Resource Area, 226 Cruz Alta Road, Taos, NM 87571; phone (505) 758–8851.

Dated: July 23, 1997.

Mike Ford,

District Manager.

[FR Doc. 97–19954 Filed 7–28–97; 8:45 am]

BILLING CODE 4310–AG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–020–1060–00]

Notice of Meeting

AGENCY: Bureau of Land Management (BLM), Montana, Miles City District, Billings Resource Area, Interior.

ACTION: Notice of meeting.

SUMMARY: The Billings Resource Area of the Miles City District will host a public hearing on the use of helicopters for the wild horse gather operation in the Pryor Mountain Wild Horse Range. The meeting will be held at the Bighorn Canyon National Recreation Area Visitor Center, in Lovell, Wyoming, on Thursday, August 14, 1997 at 7 p.m. Following the hearing, a general meeting to discuss the proposed gather operation will be held. The proposed removal operation is scheduled to begin no earlier than October 1, 1997.

DATES: Written comments on the proposal should be submitted to the address below by August 15, 1997.

ADDRESSES: Bureau of Land Management (BLM), Billings Resource Area, Linda Coates-Markle, 810 East Main, Billings, Montana 59105.

FOR FURTHER INFORMATION CONTACT: Linda Coates-Markle, Wild Horse and Burro Specialist, telephone (406) 238–1540.

SUPPLEMENTARY INFORMATION: A Draft Pryor Mountain Wild Horse Range Wild Horse Removal Plan was completed July 14, 1997 and is available for public review. Copies may be obtained from the above address.

Dated: July 22, 1997.

Janet L. Edmonds,

Acting District Manager.

[FR Doc. 97–19894 Filed 7–28–97; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–958–0777–63; GP7–0062; OR–19851 (WA)]

Public Land Order No. 7277; Revocation of Executive Order Dated January 17, 1911; Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order revokes in its entirety an Executive order which withdrew 12,438.86 acres of National Forest System lands for the Bureau of Land Management's Reservoir Site Reserve No. 1. The lands are no longer needed for this purpose and the revocation is needed to permit disposal of a portion of the land through a Forest Service exchange. This action will open the lands to surface entry and nonmetalliferous mining, unless included in existing withdrawals or other segregations of record. All of the lands have been and will remain open to metalliferous mining and mineral leasing unless closed by existing withdrawals or other segregations of record.

EFFECTIVE DATE: August 28, 1997.

FOR FURTHER INFORMATION CONTACT: Betty McCarthy, BLM Oregon/Washington State Office, P.O. Box 2965, Portland, Oregon 97208–2965, 503–952–6155.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. The Executive Order dated January 17, 1911, which established Reservoir Site Reserve No. 1, is hereby revoked in its entirety:

Willamette Meridian

Wenatchee National Forest

T. 27 N., R. 16 E.,
- Sec. 4, lots 3 and 4, S½NW¼, and SE¼;
- Sec. 5, lot 1, SW¼NE¼, and W½SE¼;
- Sec. 9, N½NE¼NE¼, NW¼SW¼NW¼NW¼, S½SW¼NW¼NW¼, S½NW¼, SW¼, S½NW¼SW¼SE¼, and SW¼SW¼SE¼;
- Sec. 10, that portion of the NW¼ lying outside HES No. 48, and those portions of the NE¼NE¼SW¼ and SE¼ lying outside HES Nos. 43 and 44;
- Sec. 13, lot 5 and Tract 37 (formerly lot 1);
- Sec. 14, lots 4, 6, and 7, and NE¼NE¼;
- Sec. 15, N½NE¼ and S½;
- Sec. 16, SW¼NE¼NE¼, NW¼NE¼, S½NE¼, NW¼, and S½;
- Sec. 17,
- Sec. 18, lots 1 to 4, inclusive, E½, and E½W½;

Sec. 20, NE¼;
Sec. 21, NW¼NE¼, S½NE¼, and NW¼;
Sec. 22, lot 3, NE¼NE¼, W½NE¼, NW¼, and SE¼;
Sec. 23, lots 1 to 5, inclusive, and S½S½;
Sec. 24, lots 1 to 4, inclusive, and S½SW¼;
Sec. 25, NE¼.
T. 28 N., R. 16 E.,
Sec. 18, lots 1 to 4, inclusive, E½W½, and that portion of the E½ lying outside HES No. 163;
Sec. 19, lots 1 to 4, inclusive, E½W½, and that portion of the E½ lying outside HES No. 164;
Sec. 20, E½SW¼ and that portion of the W½SW¼ lying outside HES No. 164;
Sec. 29, NE¼NW¼, S½NW¼NW¼, SW¼SW¼SW¼NW¼, NE¼SE¼NW¼, E½SE¼SE¼NW¼, W½SW¼, NE¼SE¼, N½NW¼SE¼, N½SE¼NW¼SE¼, SE¼SE¼NW¼SE¼, E½SE¼SE¼, N½NW¼SE¼SE¼, SE¼NW¼SE¼SE¼, E½SW¼SE¼SE¼, and that portion of the N½NW¼NW¼ lying outside HES No. 164;
Sec. 30, W½NE¼, SW¼NE¼SE¼NE¼, NW¼NW¼SE¼NE¼, S½NW¼SE¼NE¼, S½SE¼NE¼, SE¼, and that portion of the NE¼NE¼ lying outside HES No. 164;
Sec. 32, N½NW¼ and W½SW¼.
T. 26 N., R. 17 E.,
Sec. 3, lot 3, SE¼NW¼, and E½SW¼;
Sec. 8, E½SW¼ and W½SE¼;
Sec. 9, lots 1, 4, 5, 7, 10, and 11, SE¼NE¼, NE¼SE¼, and S½SE¼;
Sec. 17, NW¼NE¼.
T. 27 N., R. 17 E.,
Sec. 14, lots 1 to 4, inclusive, W½NE¼, NW¼, and W½SE¼;
Sec. 15, lots 1 to 5, inclusive, and NE¼NE¼;
Sec. 16, SW¼;
Sec. 17, S½S½;
Sec. 19, SE¼NE¼;
Sec. 20, lots 1, 2, and 3, NE¼, E½NW¼, SW¼NW¼, NE¼SW¼, N½SE¼, and SE¼SE¼;
Sec. 21, lots 1, 2, and 3, NW¼, and S½;
Sec. 22, lot 3, NE¼NE¼, S½NE¼, SE¼NW¼, N½S½, SW¼SW¼, and SE¼SE¼;
Sec. 23, W½ and S½SE¼;
Sec. 26, lots 1 and 2, and lots 6 to 11, inclusive, N½NE¼, and SW¼;
Sec. 27, lots 1, 3, 4, and 5, NW¼NW¼, NE¼SW¼, NW¼SE¼, and S½S½;
Sec. 28, lot 8;
Sec. 30, lots 2, 6, and 7, E½SW¼, and S½SE¼;
Sec. 32, N½N½;
Sec. 33, E½NE¼, NW¼NE¼, and E½NW¼;
Sec. 34, W½.

The areas described aggregate approximately 12,438.86 acres in Chelan County.

2. That portion of the NE¼ of Sec. 18, T. 28 N., R. 16 E., lying within the Glacier Peak Wilderness Area withdrawal, remains closed to operation of the public land laws, including the mining and mineral leasing laws.

3. The following described lands are included in Forest Service recreation and administrative area withdrawals and will remain closed to operation of the public land laws, including the mining laws:

T. 27 N., R. 16 E.,
Sec. 13, lot 5;
Sec. 23, lots 2, 3, 4, and 5;
Sec. 24, lots 2, 3, and 4, and SE¼SW¼.

4. The following described lands are included in two Forest Service campground withdrawals, and will remain closed to location and entry under the United States mining laws:

T. 27 N., R. 17 E.,
Sec. 27, lots 4 and 5, and NW¼NW¼;
Sec. 33, E½E½NE¼, SW¼NE¼NE¼, and NW¼SE¼NE¼.

5. At 8:30 a.m. on August 27, 1997, the lands described in paragraph 1, except as provided in paragraphs 2, 3, and 4, will be opened to such forms of disposition as may by law be made of National Forest System lands, including location and entry under the United States mining laws for nonmetalliferous minerals, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. Appropriation of lands described in this order under the general mining laws for nonmetalliferous minerals prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1994), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: July 16, 1997.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 97–19833 Filed 7–28–97; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–080–1430–00; UTU 2036, UTU 4061]

Public Land Order No. 7276; Partial Revocation of Executive Order No. 5327 and Public Land Order No. 4522; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order partially revokes an Executive order and a public land order insofar as they affect 75 acres of public land withdrawn for protection of oil shale resources. The withdrawals are no longer needed for this purpose and revocations are needed to permit disposal of the land through sale under the Recreation and Public Purposes Act, as amended. The land is temporarily closed to surface entry and mining due to a pending sale application. The land has been and will remain open to mineral leasing.

EFFECTIVE DATE: August 28, 1997.

FOR FURTHER INFORMATION CONTACT: LaVerne Steah, BLM Utah State Office, P.O. Box 45155, Salt Lake City, Utah 84145–0155, (801) 539–4114.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Executive Order No. 5327 and Public Land Order No. 4522, which withdrew public land for the protection of oil shale and associated values, are hereby revoked insofar as they affect the following described land:

Salt Lake Meridian

T. 5 S., R. 19 E.
Sec. 11, W½W½NW¼NE¼, W½NW¼SW¼NE¼, NE¼NW¼, and N½SE¼NW¼.

The area described contains 75 acres in Uintah County.

2. At 9 a.m. on August 28, 1997, the land will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 9 a.m. August 28, 1997, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

3. At 9 a.m. on August 28, 1997, the land will be opened to location and entry under the United States mining laws, subject to valid existing rights, provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. Appropriation of any of the land described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1994), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are

governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: July 16, 1997.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 97–19840 Filed 7–28–97; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of extension and revision of a currently approved collection.

SUMMARY: The Department of the Interior has submitted to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act of 1995 (Act) the collection of information discussed below. The Act requires that OMB provide interested Federal agencies and the public an opportunity to comment on information collection requests. The Act also provides that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Submit written comments by August 28, 1997.

ADDRESSES: Submit comments and suggestions directly to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of the Interior (1010–0030), 725 17th Street, N.W., Washington, D.C. 20503. Send a copy of your comments to the Rules Processing Team, Mail Stop 4020, Minerals Management Service, 381 Elden Street, Herndon, Virginia 20170–4817.

FOR FURTHER INFORMATION CONTACT: Alexis London, Rules Processing Team, Engineering and Operations Division, Minerals Management Service, telephone (703) 787–1600. You may obtain copies of the supporting statement and collection of information by contacting the MMS Information Collection Clearance Officer at (202) 208–7744.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR 250, Subpart A, General.

OMB Number: 1010–0030.

Abstract: Respondents provide information and maintain records on designations of operator; performance capabilities and standards; lease cancellations; suspensions of production or other operations; determinations of well producibility; reinjection and subsurface storage of gas; reimbursements of geological and geophysical data and information reproduction costs; accident reports; access to facilities; and crane inspection, testing, maintenance and operator qualifications. The MMS uses the information to ensure that operations in the OCS are carried out in a manner that is safe, pollution free, and does not interfere with the rights of other users in the OCS. Responses to this collection of information are mandatory. The MMS will protect proprietary information in accordance with the Freedom of Information Act and 30 CFR 250.18, Data and information to be made available to the public.

Description of Respondents: Federal OCS oil and gas and sulphur lessees.

Estimated Number of Respondents: 130.

Frequency: The reporting and recordkeeping requirements and number of responses vary for each section and are mostly on occasion or annual (see chart below).

BURDEN BREAKDOWN

Citation 30 CFR 250 subpart A	Reporting requirement	Annual frequency	Average number per year	Burden per reqmnt.	Annual burden hours
3(a)	Request approval for use of new or alternative techniques, procedures, or activities.	On occasion	7 requests	9 hours	63
3(b)	Request approval of departure from operating requirements.	Burden is included with applicable operating requirement			0
4(b)	Submit requests, applications, and notices under various regulations.	Burden is included with applicable requirement			0
7(a),(b),(f)	Apply for right of use and easement to construct and maintain off lease platforms, artificial islands, & installations & other devices.	On occasion	20 applications	5 hours	100
7(c)	Request approval for platforms, artificial islands, etc.	Burden included with 1010–0058 for Subpart I			0
8	Submit designation of operator & report change of address or notice of termination.	Exempt as defined in 5 CFR 1320.3(h)(1)			0
9	Submit designation of local agent	Burden included in 1010–0006 for 30 CFR Part 256			0
10(a),(b),(i); 13(b)(2)	Request suspension of production or operations & submit schedule of work leading to commencement.	On occasion	238 requests	10 hours	2,380
10(g),(h)(2); 12(c)(1)(i); 26.	Submit exploration & development & production plan or modification.	Burden included in 1010–0049 for 30 CFR 250, Subpart B			0
10(h)(1)	Conduct site-specific study & submit results	There have been no instances requiring this study in several years. It could be necessary if a situation occurred such as severe damage to a platform or structure caused by a hurricane or a vessel collision			0
11	Request determination of well producibility	On occasion	140 requests	3 hours	420
12(a)(1)(iv), (b),(c)(1)(ii).	Request termination of suspension & cancellation of lease.	Suspension automatically terminates when sus pended activity resumes. MMS has received no requests in recent years for termination and cancellation of a lease. Burden would be minimal			0

BURDEN BREAKDOWN—Continued

Citation 30 CFR 250 subpart A	Reporting requirement	Annual frequency	Average number per year	Burden per reqmnt.	Annual burden hours
12(f)	Request compensation for lease cancellation.	The OCSLA specifies this compensation. There have been no qualified lease cancellations in many years. Burden would be minimal			0
13(d)	Request extension of time period between operations.	On occasion	3 requests	3 hours	9
14(a)(2),(b), (c),(e),(f)	Apply for reinjection or subsurface storage of gas.	On occasion	10 applications	7.6 hours	76
15(a)	Identify with sign platforms, structures, etc., which have helicopter landing facilities.	On occasion	150 new or replacement signs.	2 hours	300
15(b)	Identify wells with paint or signs	On occasion	904 new wells	1 hour	904
16(a),(b),(c)	Request reimbursement for submitted G&G data & information.	The OCSLA specifies this reimbursement. MMS has received no reimbursement requests for post-lease G&G data & information in many years. Pre-lease reimbursement is covered in 30 CFR Part 251 (1010–0048). Burden would be minimal			0
19(a),(b)	Report accidents	On occasion	142 reports	7 hours	994
19(a)	Report spills of oil or other pollutants	Burden included in 1010–0091 for 30 CFR Part 254			0
21(c)	Request reimbursement for food, quarters, & transportation provided to MMS representatives.	The OCSLA specifies this reimbursement. MMS has received no reimbursement requests in many years. Burden would be minimal			0
22(b)	Submit information on the use of BAST, alternatives considered, & rationale.	On occasion	6 submissions	4.7 hours	28 (rounded)
23	Submit report when last well on lease ceases production.	On occasion	500 submissions	.5 hour	250
24	File appeal on orders or decisions	Exempt as defined in 5 CFR 1320.3(h)(9)			0
Total Reporting		2,120 responses		5,524.	
20(c)	Retain records of crane inspection, testing, maintenance, and crane operator qualifications for 2 years.	Annual	484 recordkeepers	6 hours	2,904
Total Recordkeeping.					2,904

Estimated Annual Burden on Respondents: Reporting and recordkeeping burden of 8,428 hours; no reporting and recordkeeping cost burden for this collection of information.

Comments: In compliance with the Paperwork Reduction Act of 1995, Section 3506(c)(2)(A), each agency must provide notice and otherwise consult with members of the public and affected agencies concerning this collection of information. Comments are specifically solicited in order to: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) evaluate the accuracy of the burden estimates for the proposed collection of information; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Submit your comments to the offices listed in the addresses section of this notice. OMB has up to 60 days to approve or disapprove the information collection, but may respond after 30 days. Therefore, in order to assure maximum consideration, OMB should receive your comments within 30 days of publication of this notice.

Bureau Clearance Officer: Jo Ann Lauterbach (202) 208–7744.

Dated: July 3, 1997.

E. P. Danenberger,

Chief, Engineering and Operations Division.

[FR Doc. 97–19955 Filed 7–28–97; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

National Park Service

Boundary Revision; Golden Gate National Recreation Area

AGENCY: National Park Service, Interior.

ACTION: Notice of Boundary Revision, Golden Gate National Recreation Area.

SUMMARY: This notice announces a revision of the boundaries of Golden Gate National Recreation Area to include within the boundaries six unimproved parcels of land adjacent to the southwest corner of the Presidio of San Francisco along Lobos Creek.

FOR FURTHER INFORMATION CONTACT: Sondra S. Humphries, Chief, Pacific Land Resources Program Center at (415) 427–1416.

SUPPLEMENTARY INFORMATION: Notice is hereby provided that the boundaries of Golden Gate National Recreation Area, established October 27, 1972, pursuant to Public Law 92–589, 86 Stat. 1299, as amended, are revised, effective as of the date of publication of this notice, to include all that certain property situated in the City and County of San Francisco, State of California, commonly referred to as Assessor's Parcels 1338–001, 1338–021, 1339–001, 1341–022, 1341–023, and 1341–024. The above parcels owned by four private parties aggregate approximately one acre and are identified as tracts 01–144, 01–145, 01–146 and 01–147 on Sheet 2 of 26, Segment Map 01, Drawing No. 641/80,046, dated April 2, 1997, and on file at the National Park Service, Pacific Land Resources Program Center, 600 Harrison Street, Suite 600, San Francisco, California 94107–1372.

Dated: April 29, 1997.

Patricia L. Neubacher,

Acting Regional Director, Pacific West Region.

[FR Doc. 97–19834 Filed 7–28–97; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before July 19, 1997. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, DC 20013–7127. Written comments should be submitted by August 13, 1997.

Patrick Andrus,

Acting Keeper of the National Register.

ALASKA

Kenai Peninsula Borough-Census Area

Sunrise City Historic District, Address Restricted, Hope vicinity, 97000892.

ARIZONA

Pima County

Tucson Warehouse Historic District, Roughly bounded by 6th St., Fourth and Toole Aves., Tucson, 97000886.

COLORADO

Denver County

Joslin Dry Goods Company Building, 934 16th St., Denver, 97000893.

FLORIDA

Polk County

Davenport Historic District, Roughly bounded by Suwannee and Orange Aves., Palmento St., and West Blvd., Davenport, 97000894.

ILLINOIS

Sangamon County

Camp Butler National Cemetery (Civil War Era National Cemeteries MPS), 5063 Camp Butler Rd., Springfield, 97000891.

MISSISSIPPI

Calhoun County

New Liberty School, Jct. of Co. Rd. 428, and Co. Rd. 427, Vardaman vicinity, 97000895.

Jones County

Fishtrap Bluff Fishweir, Address Restricted, Ellisville vicinity, 97000896.

MISSOURI

Jackson County

Fidelity National Bank and Trust Company Building, The, 911 Walnut St., Kansas City, 97000908.

OREGON

Umatilla County

Arlington Hotel (Echo and The Meadows MPS), 131 W. Main St., Echo, 97000897.

Cunha, Joseph, Farmstead (Echo and The Meadows MPS), 33263 Oregon Trail Rd., Echo vicinity, 97000898.

Echo City Hall (Echo and The Meadows MPS), 20 S. Bonanza St., Echo, 97000899.

Echo Methodist Church (Echo and The Meadows MPS), 1 Bonanza St., Echo, 97000900.

Edwards, James, Building (Echo and The Meadows MPS), 320 Main St., Echo, 97000901.

Koontz, J.H., Building (Echo and The Meadows MPS), 141 N. Main St., Echo, 97000902.

Koontz, James H. and Cynthia, House (Echo and The Meadows MPS), 210 N. Dupont St., Echo, 97000903.

Liesegang, Edward C., Building (Echo and The Meadows MPS), 211 N. Main St., Echo, 97000904.

St. Peter's Roman Catholic Church (Echo and The Meadows MPS), Jct. of Marble St. and Leezer Ave., Echo vicinity, 97000905.

Umatilla Masonic Lodge Hall (Echo and The Meadows MPS), 200 S. Dupont St., Echo, 97000906.

Union County

Union Main Street Historic District, Along Main St., between Birch and Fulton Sts., Union, 97000907.

WISCONSIN

Bayfield County

Herbster Community Center, Lenawee Rd., S of jct. of Lenawee Rd. and WI 13, Herbster, 97000888.

Door County

Thorp, Freeman and Jesse, House and Cottages, 4135 Bluff Street, Fish Creek, 97000887.

Jefferson County

City of Waterloo Carousel, 500 Park Ave., Waterloo, 97000890.

Oneida County

Boesel, Ella M., Boathouse, 9282 Country Club Rd., Minocqua, 97000889.

[FR Doc. 97–19920 Filed 7–28–97; 8:45 am]

BILLING CODE 4310–70–P

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

Notice of Public Information Collection Requirements Submitted to OMB for Review

SUMMARY: U.S. Agency for International Development (USAID) is making efforts to reduce the paperwork burden. USAID invites the general public and other Federal agencies to take this opportunity to comment on the following continuing information collections, as required by the Paperwork Reduction Act of 1995. Comments are requested concerning: (1) Whether the continuing collections of information is necessary for the proper performance of the functions of the agency, including whether information shall have practical utility; (2) the accuracy of the burden estimates; (3) ways to enhance the quality, utility, and clarity of the information collected, and (4) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

Comments regarding this information collection are best assured of having their full effect if received within 60 days of this notification. Comments should be addressed to: Ms. Sue M. Parks, Bureau for Humanitarian Response, Office of American Schools and Hospitals Abroad (BHR/ASHA), Room 100, SA–8, 703–351–0232. Copies of submission may be obtained by calling 703–516–1864.

SUPPLEMENTARY INFORMATION:

OMB Number: OMB 0412–0011.

Form Number: AID 1010–2.

Title: Application for Assistance—American Schools and Hospitals Abroad.

Type of Submission: Renew.

Purpose: USAID finances grant assistance to U.S. founders or sponsors who apply for grant assistance from ASHA on behalf of their institutions overseas. ASHA is a competitive grants program. The office of ASHA is charged with judging which applicants may be eligible for consideration and receive what amounts of funding for what purposes. To aid in such determination, the Office of ASHA has established guidelines as the basis for deciding upon the eligibility of the applicants and the resolution on annual grant awards. These guidelines are published in the FR Doc. 79–36221.

Annual Reporting Burden:

Respondents: 85.

Average hrs per response: 12.

Annual Burden hours: 1,020.

Dated: July 16, 1997.

Willette Smith,

Acting Chief, Information Records Division, Bureau for Management, Office of Administrative Services.

[FR Doc. 97–19841 Filed 7–28–97; 8:45 am]

BILLING CODE 6116–01–M

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

F.C.S.C. Meeting Notice No. 19–97

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 504) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings and oral hearings for the transaction of Commission business and other matters specified, as follows:

Dates and Times: Monday, August 4, 1997, 9:30 a.m. to 5:00 p.m.; Wednesday, August 6, 1997, 9:30 a.m. to 5:00 p.m.; Friday, August 8, 1997, 9:30 a.m. to 5:00 p.m.; Monday, August 11, 1997, 9:30 a.m. to 5:00 p.m.; Wednesday, August 13, 1997, 9:30 a.m. to 5:00 p.m.; Friday, August 15, 1997, 9:30 a.m. to 5:00 p.m.; Monday, August 18, 1997, 9:30 a.m. to 5:00 p.m.; Wednesday, August 20, 1997, 9:30 a.m. to 5:00 p.m.; Friday, August 22, 1997, 9:30 a.m. to 5:00 p.m.; Monday, August 25, 1997, 9:30 a.m. to 5:00 p.m.; Wednesday, August 27, 1997, 9:30 a.m. to 5:00 p.m.; Friday, August 29, 1997, 9:30 a.m. to 5:00 p.m.

Subject Matter: (1) Oral Hearings and Hearings on the Record on Objections to the Commission's Proposed Decision on the Scope of the Holocaust Survivors Claims Program, Decision No. HS–I, issued June 16, 1997; (2) Oral Hearings and Hearings on the Record on Objections to Individual Proposed Decisions on Claims of Holocaust Survivors Against Germany; (3) Consideration of Individual Proposed Decisions on Claims of Holocaust Survivors Against Germany; (4) Issuance of Final Decision on the Scope of the Holocaust Survivors Claims Program, Decision No. HS–II; (5) Issuance of Individual Final Decisions on Claims of Holocaust Survivors Against Germany.

Status: Closed.

All meetings are held at the Foreign claims Settlement Commission, 600 E Street, NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Administrative Officer, Foreign Claims Settlement Commission, 600 E Street, NW., Room 6002, Washington, DC 20579. Telephone: (202) 616–6988.

Dated at Washington, DC, July 25, 1997.

Judith H. Lock,

Administrative Officer.

[FR Doc. 97–20066 Filed 7–25–97; 2:15 pm]

BILLING CODE 4410–01–P

DEPARTMENT OF JUSTICE

Office of Juvenile Justice and Delinquency Prevention

Agency Information Collection Activities; New Collection: Comment Request

ACTION: Notice of information collection under review: The Second National Incidence Studies of Missing, Abducted, Runaway, and Thrownaway Children (NISMART 2).

The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted until September 29, 1997.

We are requesting written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following points:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used;

3. Enhance the quality, utility, and clarity of the information being sought;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to Ms. Doris Anderson, Research and Program Development Division (RPD), Office of Juvenile Justice and Delinquency Prevention (OJJDP), 633 Indiana Ave, NW, Washington, DC 20531. If you have additional comments or suggestions, or if you want additional information, please contact Ms. Barbara Allen-Hagen, Research and Program Development Division (RPD), Office of Juvenile Justice and Delinquency Prevention (OJJDP), 633 Indiana Ave, NW, Washington, DC 20531.

Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, Washington Center, 1001 G Street, NW, Washington, D.C. 20530.

Overview of this information collection:

1. Type of information collection: New collection.

2. Title of the Form/Collection: The Second National Incidence Studies of Missing, Abducted, Runaway, and Thrownaway Children (NISMART 2).

3. Agency form number: None; Applicable component of the Department of Justice sponsoring the collection: Department of Justice (DOJ), Office of Justice Programs (OJP), Office of Juvenile Justice and Delinquency Prevention (OJJDP).

4. Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Individuals or households. Other: State, local, tribal governments; Not for profit pursuant to the Missing Children's Assistance Act, Title IV, section 404(b)(3) of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended, 42 U.S.C. 5773(b)(3). OJJDP is required to conduct periodic studies of the incidence of missing children. The purpose of these studies is to develop reliable and valid statistics on the incidence of children who are missing, abducted, runaways, or thrownaway in the course of a given year, as well as the number of these children who are recovered.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 75,000 respondents at 2.5 minutes per response; 22,000 respondents at 20 minutes per response; 9500 respondents at 10 minutes per response; 2500 respondents at 45 minutes per response; 50 respondents at 16 hours per response.

6. An estimate of the total public burden (in hours) associated with the collection: 14,716 burden hours.

Public comment on the proposed information collection is strongly encouraged.

Dated: July 23, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–19826 Filed 7–28–97; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed extension collection of the MA 8–7, Transmittal for Unemployment Insurance Materials.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before September 29, 1997. The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility,and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

ADDRESSES: Loryn M. Lancaster, Room C–4512, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210, phone (202) 219–5200, extension 368 (this is not a toll-free number), internet address lancasterl@doleta.gov, fax (202) 219–8506.

SUPPLEMENTARY INFORMATION:

I. Background

Department of Labor, Employment and Training Administration regulations, 20 CFR 601, Administrative Procedures, contains collection of information requirements at Sections 601.2 and 601.3. Section 601.2 requires States to submit copies of their unemployment compensation laws for approval by the Secretary of Labor so that the Secretary may determine the status of State laws and plans of operation. Section 601.3 requires States to ''submit all relevant State materials such as statutes, executive and administrative orders, legal opinions, rules, regulations, interpretations, court decisions, etc.'' These materials are used by the Secretary to determine whether the State law contains provisions required by Section 3304(a) of the Internal Revenue Code of 1986. Grants of funds are made to States for the administration of their employment security laws if their unemployment compensation laws and their plans of operation for public employment offices meet required conditions of Federal laws.

The information transmitted by Form MA 8–7 is used by the Secretary to make findings (as specified in the above cited Federal laws) required for certification to the Secretary of the Treasury for payment to States or for certification of the State law for purposes of additional tax credit. If this information is not available, the Secretary cannot make such certifications.

To facilitate transmittal of required material, the Department prescribes the use of Form MA 8–7, Transmittal for Unemployment Insurance Materials. This simple checkoff form is used by the States to identify material being transmitted to the National Office and allows the material to be routed to appropriate staff for prompt action.

II. Current Actions

States could not be certified if this information were not collected and Form MA 8–7 greatly facilitates its receipt.

Type of Review: Extension without change.

Agency: Employment and Training Administration.

Title: Transmittal for Unemployment Insurance Materials.

OMB Number: 1205–0222.

Agency Number: MA 8–7.

Affected Public: State Governments.

Cite/Reference/Form/etc: MA 8–7.

Total Respondents: 53.

Frequency: As needed.

Total Responses: 3,120.

Average Time per Response: 1 minute.

Estimated Total Burden Hours: 52 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintaining): $1,040.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: July 23, 1997.

Grace A. Kilbane,

Director, Unemployment Insurance Service.

[FR Doc. 97–19944 Filed 7–28–97; 8:45 am]

BILLING CODE 4510–30–M

LIBRARY OF CONGRESS

[Docket No. 97–1]

Competition; National Digital Library Program

AGENCY: Library of Congress.

ACTION: Notice of competition.

SUMMARY: This Notice of Competition announces that the Library of Congress, with a gift from Ameritech, is sponsoring a competition to enable United States public, research, and academic libraries, museums, historical societies and archival institutions (except Federal institutions) to create digital collections of primary resources for distribution on the Internet. In the 1997–98 competition, applications will be limited to collections of textual and graphic materials that illuminate the period 1763–1920 and that complement and enhance the American Memory collections already mounted in the National Digital Library. Awards will be made of up to $75,000 to individual institutions and up to $150,000 to eligible consortia for projects that can be accomplished in twelve to eighteen months.

DATES: Applications must be postmarked by November 3, 1997.

ADDRESSES: Submit applications to the Library of Congress, Washington DC 20540–1340.

FOR FURTHER INFORMATION CONTACT: Bonnie Magness-Gardiner. Tel: (202)

707–1087. Fax: (202) 252–3249. E-mail: lc__ameritech@loc.gov. Http://lcweb2.loc.gov/ammem/award/

SUPPLEMENTARY INFORMATION: The National Digital Library is envisioned as a distributed collection of converted library materials and digital originals to which many American institutions will contribute. The Library of Congress's contribution to this World Wide Web-based virtual library is called American Memory and is created by the Library's National Digital Library Program.

Non-profit cultural repositories in the United States with collections of primary resources that are significant for education and research in United States history and culture are eligible to apply to the Library of Congress/Ameritech National Digital Library competition. Collections that are digitized with awards from this competition must be distributable on the Internet.

Applications from Association of Research Libraries (ARL) and non-ARL institutions will be evaluated separately, in order to encourage applications from a variety of institutions. In the final selection among meritorious projects some consideration will be given to the type and size of institution and its geographical location, and to certain themes described in the Guidelines, but the principal criteria will be:

- The significance of the collection's content for understanding United States history and culture, as well as its breadth of interest and utility to students and the general public.
- The availability and usability of aids to intellectual access that can be integrated into the American Memory resource.
- The technical and administrative viability of the project's plan of work in relation to the scope of the project.

Applications will be evaluated by scholars, educators, librarians, archivists, administrators, and technical specialists external to the Library of Congress. Evaluators will be convened by George Farr, Director of the Division of Preservation and Access of the National Endowment for the Humanities and by Deanna Marcum, President of the Council on Library and Information Resources.

Only costs directly associated with digital conversion may be included in the request. Equipment may not be purchased with award funds. Detailed Guidelines and Application Instructions are available from the telephone contact and Web site listed above.

Dated: July 17, 1997.

Approved by:

James H. Billington,

Librarian of Congress.

[FR Doc. 97–19842 Filed 7–28–97; 8:45 am]

BILLING CODE 1410–04–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 97–101]

Information Collection: Submission for OMB Review, Comment Request

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of agency report forms under OMB review.

SUMMARY: The National Aeronautics and Space Administration has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Comments on this proposal should be received on or before August 28, 1997.

ADDRESSES: All comments should be addressed to Mr. Harry Lupuloff, Office of General Counsel, Code GP, National Aeronautics and Space Administration, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Ms. Carmela Simonson, Office of the Chief Information Officer, (202) 358–1223.

Reports: None.

Title: Patent License Report.

OMB Number: 2700–0010.

Type of review: Extension.

Need and Uses: Each licensee is required to report annually on its activities in commercializing its licensed inventions and any royalties due. NASA uses information collected to monitor the activities of its licensees.

Affected Public: Individuals or households, business or other for-profit.

Number of Respondents: 100.

Responses Per Respondent: 1.

Annual Responses: 100.

Hours Per Request: 30 min.

Annual Burden Hours: 50.

Frequency of Report: Annually.

Donald J. Andreotta,

Deputy Chief Information Officer (Operations), Office of the Administrator.

[FR Doc. 97–19822 Filed 7–28–97; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (97–100)]

Information Collection: Submission for OMB Review, Comment Request

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of agency report forms under OMB review.

SUMMARY: The National Aeronautics and Space Administration has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Comments on this proposal should be received on or before August 28, 1997.

ADDRESSES: All comments should be addressed to Mr. Harry Lupuloff, Office of the General Counsel, Code GP, National Aeronautics and Space Administration, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Ms. Carmela Simonson, Office of the Chief Information Officer, (202) 358–1223.

Reports: None.

Title: Application for a Patent License.

OMB Number: 2700–0039.

Type of Review: Extension.

Need and Uses: The information supplied is used by the NASA Associate General Counsel to make agency determinations that NASA should either grant or deny a request for a patent license, and whether the license should be exclusive, partially exclusive, or nonexclusive.

Affected Public: Individuals or households, business or other for-profit.

Number of Respondents: 45.

Responses Per Respondent: 1.

Annual Responses: 45.

Hours Per Request: 6.

Annual Burden Hours: 270.

Frequency of Report: Annually.

Donald J. Andreotta,

Deputy Chief Information Officer (Operations), Office of the Administrator.

[FR Doc. 97–19823 Filed 7–28–97, 8:45 am]

BILLING CODE 7510–01–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration, Office of Records Services

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Records schedules identify records of sufficient value to warrant preservation in the National Archives of the United States. Schedules also authorize agencies after a specified period to dispose of records lacking administrative, legal, research, or other value. Notice is published for records schedules that propose the destruction of records not previously authorized for disposal, or reduce the retention period for records already authorized for disposal. NARA invites public comments on such schedules, as required by 44 U.S.C. 3303a(a).

DATES: Requests for copies must be received in writing on or before September 12, 1997. Once the appraisal of the records is completed, NARA will send a copy of the schedule. The requester will be given 30 days to submit comments.

ADDRESSES: Address requests for single copies of schedules identified in this notice to the Civilian Appraisal Staff (NWRC), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Requesters must cite the control number assigned to each schedule when requesting a copy. The control number appears in the parentheses immediately after the name of the requesting agency.

FOR FURTHER INFORMATION CONTACT: Michael L. Miller, Director, Records Management Programs, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001, telephone (301) 713–7110.

SUPPLEMENTARY INFORMATION: Each year U.S. Government agencies create billions of records on paper, film, magnetic tape, and other media. In order to control this accumulation, agency records managers prepare records schedules specifying when the agency no longer needs the records and what happens to the records after this period. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. These comprehensive schedules provide for the eventual transfer to the National Archives of historically valuable records and authorize the disposal of all other records. Most schedules, however, cover records of only one office or program or a few series of records, and many are updates of previously approved schedules. Such schedules also may include records that are designated for permanent retention.

Destruction of records requires the approval of the Archivist of the United States. This approval is granted after a thorough study of the records that takes into account their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and historical or other value.

This public notice identifies the Federal agencies and their subdivisions requesting disposition authority, includes the control number assigned to each schedule, and briefly describes the records proposed for disposal. The records schedule contains additional information about the records and their disposition. Further information about the disposition process will be furnished to each requester.

Schedules Pending

1. Department of Agriculture, Economic Research Service (N1–354–97–1). Project files of a study related to the urbanization of rural land.

2. Department of Commerce (N1–40–97–1). Pioneer Fund grant application files and general program correspondence.

3. Department of Health and Human Services, National Institutes of Health (N1–443–97–2). Audit case files and working papers.

4. Panama Canal Commission (N1–185–97–23). Miscellaneous administrative records stored in agency records center.

5. Surface Transportation Board (N1–134–96–3). Rate bureau agreement files.

6. Tennessee Valley Authority (N1–142–97–7). Reduction in the retention period for nuclear plant air/water quality data charts.

7. Tennessee Valley Authority (N1–142–93–7). Records relating to procurement, production and stockpiling of fuel, waste disposal and environmental monitoring at fossil fuel plants.

8. Tennessee Valley Authority (N1–142–93–14). Records relating to the test demonstration farm program.

9. Tennessee Valley Authority (N1–142–97–15). Calendars of Board members that lack substantive information.

10. Tennessee Valley Authority (N1–142–97–17). Correspondence files of the Office of Employee Relations.

11. Tennessee Valley Authority (N1–142–97–20). Water data instrument calibration, monitoring and reporting records.

12. United States International Trade Commission (N1–81–97-1). Case files maintained by the Office of the Secretary on investigations of possible violations of administrative protective orders and commission rules.

Dated: July 22, 1997

Michael J. Kurtz,

Assistant Archivist, for Record Services—Washington, DC.

[FR Doc. 97–19923 Filed 7–28–97; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT: Nancy E. Weiss, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, D.C. 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency the grand applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; or (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that this meeting will be closed to the public pursuant to subsections (c) (4) and (6) of section 552b of Title, United States Code.

1. *Date:* August 1, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.

Program: This meeting will review applications for Fellowships for College Teachers and Independent Scholars in American Studies, Rhetoric, Communication and Media, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

2. *Date:* August 5, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review application for Fellowships for University Teachers in Philosophy, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

3. *Date:* August 6, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowships for University Teachers in Religious Studies, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

4. *Date:* August 7, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowship for College Teachers and Independent Scholars in Sociology, Psychology and Education, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

5. *Date:* August 11, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowships for University Teachers in Anthropology, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

6. *Date:* August 11, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications for Fellowships for University Teachers in Classical, Medieval, and Renaissance Studies, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

7. *Date:* August 12, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowships for University Teachers in Art and Architectural History, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

8. *Date:* August 12, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications for Fellowships for College Teachers and Independent Scholars in Art History, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

9. *Date:* August 13, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowships for College Teachers and Independent Scholars in Ancient, Medieval, and Early Modern Studies, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

10. *Date:* August 14, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowships for University Teachers in Asian, African, and Near Eastern Studies, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

11. *Date:* August 14, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications for Fellowships for College Teachers and Independent Scholars in American Literature, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

12. *Date:* August 15, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowships for University Teachers in American Literature, Linguistics, and Literary Criticism, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

13. *Date:* August 18, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowships for College Teachers and Independent Scholars in British Literature, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

14. *Date:* August 19, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications for Fellowships for University Teachers in British Literature, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

15. *Date:* August 21, 1997.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Fellowships for College Teachers and Independent Scholars in Political Science, International Affairs, and Jurisprudence, submitted to the Division of Research and Education for projects at the May 1, 1997 deadline.

Nancy E. Weiss,
Advisory Committee Management Officer.

[FR Doc. 97–19900 Filed 7–28–97; 8:45 am]
BILLING CODE 7536–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–443 (License No. NPF–86)]

North Atlantic Energy Service Corporation and Great Bay Power Corporation; (Seabrook Station, Unit No. 1)

Exemption

I.

Great Bay Power Corporation (Great Bay) is the holder of a 12.1324-percent ownership interest in Seabrook Station, Unit No. 1 (Seabrook). Its interest in Seabrook is governed by License No. NPF–86 issued by the U.S. Nuclear Regulatory Commission (the Commission or NRC), pursuant to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR part 50), on March 15, 1990, in Docket No. 50–443. Under this license, only North Atlantic Energy Service Corporation (North Atlantic), acting as agent and representative of 11 joint owners listed in the license, has authority to operate Seabrook. Seabrook is located in Rockingham County, New Hampshire. The license provides, among other things, that it is subject to all rules, regulations, and orders of the NRC now or hereafter in effect.

II.

Great Bay was established in 1994 as a successor to EUA Power Corporation, which had filed for reorganization under Chapter 11 of the U.S. Bankruptcy Code. Great Bay is a non-operating, 12.1324-percent co-owner of Seabrook and sells its proportionate share of power from Seabrook on the wholesale electricity market. In January 1997, Great Bay became a wholly owned subsidiary of BayCorp Holdings, Ltd. (BayCorp).

By letter dated May 8, 1996, North Atlantic requested, for itself and as agent for the joint owners of Seabrook, approval of the indirect transfer of control of Great Bay's interest in Operating License NPF–86 through the formation of a holding company above Great Bay. In connection with its review of the requested action, the NRC staff determined that Great Bay does not

meet the definition of ''electric utility'' as provided in 10 CFR 50.2. As a non-electric utility, Great Bay must meet the requirements of 10 CFR 50.75(e)(2) for assurance for decommissioning funding. In Great Bay's case, a surety method would be required to supplement Great Bay's existing external sinking fund.[1] On January 22, 1997, the Commission issued a 6-month temporary exemption from the requirements of 10 CFR 50.75(e)(2) to North Atlantic and Great Bay, thereby allowing Great Bay an opportunity to obtain a surety method, and to allow the Commission to approve, without further delay, the indirect transfer of control permitting Great Bay to become a wholly owned subsidiary of BayCorp, which restructuring the staff believed would likely enhance Great Bay's financial viability.

On February 21, 1997, Great Bay requested reconsideration of the staff's finding that Great Bay does not meet the NRC's definition of ''electric utility,'' and on June 4 and 16, 1997, Great Bay submitted supplemental financial information to support its request. Also included in the June 4 submittal was a request that the NRC consider granting an extension to the temporary exemption as an alternative to reconsidering at this time whether Great Bay is an electric utility under the NRC's definition.

III

''Electric utility'' is defined at 10 CFR 50.2 as ''* * * any entity that generates or distributes electricity and which recovers the cost of this electricity, either directly or indirectly, through rates established by the entity itself or by a separate regulatory authority.'' As required by 10 CFR 50.75, an entity that is not an electric utility must provide a financial assurance mechanism for decommissioning funding purposes in the form of prepayment, or an external sinking fund coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the external sinking fund. Electric utilities do not have to obtain a surety instrument to compensate for balances in the external sinking fund that are below the total estimated cost of decommissioning.

In determining originally that Great Bay is not an electric utility, the staff took note of the fact that Great Bay sells most of its share of power from Seabrook on the spot market at market-based rates. As Great Bay notes, the Federal Energy Regulatory Commission (FERC) has ''accepted'' Great Bay's tariffs providing for market-based rates without regard to whether sales of power are through contracts of varying lengths or on the spot market. However, the FERC has not ''established'' rates based on a traditional ratemaking process that provides for the recovery of reasonable and prudently incurred costs as an underlying objective. It is upon this traditional ratemaking process that the NRC's definition of electric utility is based.

There is no distinction between long-term and short-term sales in connection with the definition of electric utility, as Great Bay correctly points out in its February 21 submittal. To the extent the staff previously has suggested that there is any such distinction bearing on whether Great Bay met the definition of electric utility, the staff takes this opportunity to clarify that the definition of electric utility hinges solely upon whether or not an entity sells power at rates based on and established through a traditional reasonable and prudent cost-of-service ratemaking process. Although, as Great Bay argues, FERC may ''accept'' market-based tariffs consistent with FERC's statutory responsibilities to ensure that rates are just and reasonable, the FERC's fulfillment of its responsibilities does not necessarily mean that the particular electricity seller involved thereby meets the NRC's definition of electric utility.

Great Bay has cited the staff's earlier statements concerning the status of Great Bay as an electric utility immediately following bankruptcy proceedings involving its predecessor EUA Power Corporation. Although at one time the staff believed Great Bay to be an electric utility, upon further analysis the staff has concluded that if Great Bay or its predecessor did not sell power at rates established by FERC through a traditional cost-of-service ratemaking process, that fact alone would have compelled a finding that Great Bay was not an electric utility. Thus, although the staff's recent reasoning for its original conclusion that Great Bay is not an electric utility did not focus on whether in fact rates were being established through a traditional cost-of-service ratemaking process, the staff's analysis now compels the same conclusion.

Great Bay states that it recovers the cost of the electricity it sells. Although the staff agrees that Great Bay has provided evidence that it can generate sufficient cash to pay for its share of Seabrook-related expenses, Great Bay has not indicated that it will recover full costs, including non-cash costs. The NRC's definition of electric utility, again, is based on cost recovery as a result of the action of a independent rate-setting authority, such as FERC, rather than merely a positive cash flow resulting from then favorable market conditions.

Great Bay has provided evidence that it will continue to be able to fund its proportionate share of operating costs and decommissioning funding for Seabrook for the next 5 years. After reviewing Great Bay's current and projected financial statements submitted on June 4, 1997, the staff concludes that it appears Great Bay will be able to generate cash flow in excess of that needed to fund its proportionate share of operating costs and decommissioning funding obligations. Great Bay has projected operating income and cash flow based on what appear to be reasonable projections of the spot market price of power from Seabrook through 2001. The projections indicate that Great Bay very likely will be able to meet its operating and decommissioning cost obligations for Seabrook through 2001 and likely will have excess cash to meet many unforeseen contingencies. However, Great Bay's present unfunded decommissioning liability for its share of Seabrook is approximately $47.2 million[2] which is in excess of Great Bay's present working capital of about $30 million.[3] Thus, in the near term, a permanent shutdown, and possibly an extended temporary shutdown, of Seabrook would mean that Great Bay would have difficulty meeting its operational and decommissioning funding obligations for Seabrook.

In response to the January 22, 1997, temporary exemption, Great Bay initiated efforts to find available and economically feasible decommissioning funding assurance arrangements. In its

[1] New Hampshire statutes provide for the establishment of a Nuclear Decommissioning Financing Fund (the Fund) in the office of the State Treasurer for each nuclear electric generating facility in the state. New Hampshire statutes also provide for the establishment of a Nuclear Decommissioning Financing Committee (NDFC) with the responsibility to review the adequacy of the Fund periodically and to establish or revise the funding schedule. Each joint owner is required by the Seabrook Joint Ownership Agreement to pay monthly at least their respective ownership share of decommissioning costs into the Fund as established by the NDFC funding schedule.

[2] Great Bay's share of currently estimated decommissioning costs is approximately $53.9 million, and Great Bay has already paid approximately $6.7 million into the decommissioning fund.

[3] As part of the EUA Power bankruptcy settlement, Eastern Utility Associates (EUA), the former parent of Great Bay's predecessor, EUA Power, has guaranteed a maximum of $10 million at the time of decommissioning to make up for any shortfall in Great Bay's payments for its decommissioning obligation.

June 4, 1997, submittal, Great Bay reported that underwriting specifications had been prepared and issued to the insurance market by AON Risk Services. Subsequently, on July 7, 1997, Great Bay reported upon the status of the efforts to locate a suitable assurance arrangement. Great Bay reported that a surety bond does not appear to be available, and the only insurance mechanism available to Great Bay at the present time is for Great Bay to prefund its entire outstanding decommissioning obligation. Great Bay asserts that because there is no pool of similarly situated entities requiring decommissioning funding assurance, arrangements such as surety bonds for such entities are unavailable. Great Bay asserts further that prefunding the entire obligation would put Great Bay at an undue competitive disadvantage.

Great Bay appears to have made a good faith effort to secure a surety bond at reasonable cost but has been unsuccessful in this effort so far, and it does not appear that Great Bay feasibly can meet the NRC's requirement that non-electric utility power reactor licensees obtain a surety bond or some other third-party guarantee mechanism to provide decommissioning funding assurance.

IV.

In consideration of the foregoing, the Commission is granting an extension to the temporary exemption issued to Great Bay and North Atlantic on January 22, 1997. This extension to the temporary exemption from the requirements of 10 CFR 50.75(e)(2) is granted to allow Great Bay more time in which to obtain the additional assurance for decommissioning funding required by the regulation.

However, in view of revisions to 10 CFR 50.2 and 10 CFR 50.75 now being considered by the Commission, this exemption shall expire 90 days following the date any revisions to 10 CFR 50.2 and 10 CFR 50.75 become final agency action, or 1 year from the date of issuance of this exemption, whichever date is sooner.

The Commission has determined that pursuant to 10 CFR 50.12(a)(1), this exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission further has determined that special circumstances as provided in 10 CFR 50.12(a)(2)(ii) and 10 CFR 50.12(a)(2)(v) are present.

Under criterion (ii), special circumstances exist in that application of the regulation in this particular circumstance is not necessary, for the period of the exemption, to achieve the underlying purpose of the rule, which is to provide additional assurance that funds will be available for decommissioning at the end of the license term or in the event of a premature shutdown. In this instance, Great Bay's projected income and cash flow indicate that Great Bay very likely will be able to meet its operating costs and monthly decommissioning fund payments for Seabrook through 2001. Furthermore, Great Bay's past contributions to the existing sinking fund along with its present working capital and its former corporate parent's guarantee, would currently cover nearly three quarters of Great Bay's proportionate share of Seabrook decommissioning costs.

Furthermore, application of the requirements of 10 CFR 50.75(e)(2) at this time would not serve the underlying purpose of the rule. The regulation would require Great Bay to prefund the remaining $47.2 million decommissioning obligation or to obtain a surety bond or other third-party guarantee mechanism for the unfunded amount. No surety arrangement appears to be available to Great Bay at this time other than to fully fund or collateralize the insurer for the entire obligation which would make it difficult, if not impossible, for Great Bay to meet its day-to-day obligations. Thus, the underlying purpose of the rule would not be served by attempting to apply the rule under these circumstances.

Under criterion (v), special circumstances exist because the exemption provides only temporary relief from the applicable regulation(s), and Great Bay has made a good faith effort to comply with 10 CFR 50.75 by continuing to make payments into an external sinking fund while making good faith efforts to locate a suitable assurance mechanism.

Because this exemption is based on financial circumstances and projections that are subject to change and current market conditions for obtaining surety methods that are subject to change, this exemption is subject to the following conditions:

A. Great Bay is to continue efforts with due diligence to obtain a suitable decommissioning funding assurance arrangement that will meet the requirements of 10 CFR 50.75(e)(2) and is to provide a written report 6 months from the date of issuance of this exemption to the Director, Office of Nuclear Reactor Regulation, of the efforts underway and the progress made to obtain a suitable decommissioning funding assurance arrangement.

B. Great Bay shall provide the Director, Office of Nuclear Reactor Regulation, its next four unconsolidated quarterly financial reports, including statements of income and cash flow, and balance sheets within 45 days of the close of each calendar quarter.

C. In the event any circumstance or condition develops that threatens Great Bay's present or future ability to meet its decommissioning funding obligation, or if Great Bay is in default of any monthly payment to the Fund, Great Bay and North Atlantic are to inform the Director, Office of Nuclear Reactor Regulation, immediately in writing.

Pursuant to 10 CFR 51.32, the Commission has determined that granting this Exemption will not have a significant effect on the quality of the human environment (62 FR 39285).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 23rd day of July 1997.

For the Nuclear Regulatory Commission.

Samuel J. Collins,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 97–19930 Filed 7–28–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–272 and 50–311, etc.]

Public Service Electric & Gas Co., et al; Environmental Assessment and Finding of No Significant Impact

In the matter of: Public Service Electric & Gas Company, Philadelphia Electric Company, Delmarva Power and Light Company, Atlantic City Electric Company, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Docket Nos. 50–272 and 50–311; and Public Service Electric & Gas Company, Atlantic City Electric Company, Hope Creek Generating Station; Docket No. 50–354; Environmental assessment and finding of no significant impact.

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from certain requirements of its regulations for Facility Operating License Nos. DPR–70, DPR–75, and NPF–57, issued to Public Service Electric & Gas Company (PSE&G, the licensee), for operation of the Salem Nuclear Generating Station, Units 1 and 2, and Hope Creek Generating Station (Salem/Hope Creek), respectively.

The facilities consist of two pressurized water reactors, Salem Units 1 and 2, and a boiling water reactor, Hope Creek, at the licensee's site located in Salem County, New Jersey.

Environmental Assessment

Identification of Proposed Action

The proposed action would allow implementation of a hand geometry biometric system of site access control such that photograph identification badges can be taken offsite.

The proposed action is in accordance with the licensee's application dated January 17, 1997, for exemption from certain requirements of 10 CFR 73.55, ''Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage.''

The Need for the Proposed Action

Pursuant to 10 CFR 73.55, paragraph (a), ''General performance objective and requirements,'' the licensee shall establish and maintain an onsite physical protection system and security organization.* * *''

Paragraph (1) of 10 CFR 73.55(d), ''Access Requirements,'' specifies that ''licensee shall control all points of personnel and vehicle access into a protected area.* * *'' It is specified in 10 CFR 73.55(d)(5) that ''A numbered picture badge identification system shall be used for all individuals who are authorized access to protected areas without escort.'' It also states that an individual not employed by the licensee (i.e., contractors) may be authorized access to protected areas without escort provided the individual ''receives a picture badge upon entrance into the protected area which must be returned upon exit from the protected area.* * *''

Currently, unescorted access into protected areas of the Salem/Hope Creek site is controlled through the use of a photograph on a combination badge and keycard. (Hereafter, these are referred to as a ''badge''). The security officers at the entrance station use the photograph on the badge to visually identify the individual requesting access. The badges for both licensee employees and contractor personnel who have been granted unescorted access are issued upon entrance at the entrance/exit location and are returned upon exit. The badges are stored and are retrievable at the entrance/exit location. In accordance with 10 CFR 73.55(d)(5), contractor individuals are not allowed to take badges offsite. In accordance with the plants' physical security plans, neither licensee employees nor contractors are allowed to take badges offsite.

The licensee proposes to implement an alternative unescorted access control system which would eliminate the need to issue and retrieve badges at the entrance/exit location and would allow all individuals with unescorted access to keep their badges with them when departing the site.

An exemption from 10 CFR 73.55(d)(5) is required to permit contractors to take their badges offsite instead of returning them when exiting the site.

Environmental Impacts of the Proposed Action

Under the proposed alternative unescorted access control system, each individual who is authorized for unescorted entry into protected areas would have the physical characteristics of their hand (hand geometry) registered with their badge number in the access control system. When an individual enters the badge into the card reader and places the hand on the measuring surface, the system would record the individual's hand image. The unique characteristics of the extracted hand image would be compared with the previously stored template to verify authorization for entry. Individuals, including licensee employees and contractors, would be allowed to keep their badge with them when they depart the site.

Based on a Sandia report entitled ''A Performance Evaluation of Biometric Identification Devices'' (SAND91—0276 UC—906 Unlimited Release, Printed June 1991), and on its experience with the current photo-identification system, the licensee stated that the false acceptance rate of the proposed hand geometry system is comparable to that of the current system. The licensee stated that the use of the badges with the hand geometry system would increase the overall level of access control. Since both the badge and hand geometry would be necessary for access into the protected area, the proposed system would provide for a positive verification process. Potential loss of a badge by an individual, as a result of taking the badge offsite, would not enable an unauthorized entry into protected areas. The licensee will implement a process for testing the proposed system to ensure continued overall level of performance equivalent to that specified in the regulation. The Physical Security Plan for the Salem/Hope Creek site will be revised to include implementation and testing of the hand geometry access control system and to allow licensee employees and contractors to take their badges offsite.

The access process will continue to be under the observation of security personnel. A numbered picture badge identification system will continue to be used for all individuals who are authorized access to protected areas without escorts. Badges will continue to be displayed by all individuals while inside the protected area.

The change will not increase the probability or consequences of accidents, no changes are being made in the types of any effluent that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluent and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. The principal alternative to the action would be to deny the request. Such action would not change any current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the ''Final Environmental Statement related to the operation of Hope Creek Generating Station,'' NUREG–1074, dated December 1984 or ''Final Environmental Statement related to the operation of Salem Nuclear Generating Station Units 1 and 2,'' dated April 1973.

Agencies and Persons Consulted

In accordance with its stated policy, on February 19, 1997, the staff consulted with the New Jersey State Official, Mr. Dennis Zannoni, of the New Jersey Department of Environmental Protection and Energy, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have

a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated January 17, 1997, which is available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document rooms located at the Salem Free Public Library, 112 West Broadway, Salem, New Jersey, for Salem and at the Pennsville Public Library, 190 S. Broadway, Pennsville, New Jersey, for Hope Creek.

Dated at Rockville, Maryland, this 23rd day of July 1997.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director Project Directorate, I–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 97–19932 Filed 7–28–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–413 and 50–414]

Duke Power Company, et al.; Catawba Nuclear Station, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from certain requirements of its regulations to Facility Operating License Nos. NPF–35 and NPF–52, issued to Duke Power Company, et al. (the licensee), for operation of the Catawba Nuclear Station, Units 1 and 2, located in York County, South Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action would exempt the licensee from the requirements of 10 CFR 70.24, which requires a monitoring system that will energize clear audible alarms if accidental criticality occurs in each area in which special nuclear material is handled, used, or stored. The proposed action would also exempt the licensee from the requirements to maintain emergency procedures for each area in which this licensed special nuclear material is handled, used, or stored to ensure that all personnel withdraw to an area of safety upon the sounding of the alarm, to familiarize personnel with the evacuation plan, and to designate responsible individuals for determining the cause of the alarm, and to place radiation survey instruments in accessible locations for use in such an emergency.

The proposed action is in response to the licensee's application dated February 4, 1997, as supplemented by letter on March 19, 1997.

The Need for the Proposed Action

The purpose of 10 CFR 70.24 is to ensure that if a criticality were to occur during the handling of special nuclear material, personnel would be alerted to that fact and would take appropriate action. At a commercial nuclear power plant the inadvertent criticality with which 10 CFR 70.24 is concerned could occur during fuel handling operations. The special nuclear material that could be assembled into a critical mass at a commercial nuclear power plant is in the form of nuclear fuel; the quantity of other forms of special nuclear material that is stored on site is small enough to preclude achieving a critical mass. Because the fuel is not enriched beyond 5.0 weight percent Uranium-235 and because commercial nuclear plant licensees have procedures and features designed to prevent inadvertent criticality, the staff has determined that it is unlikely that an inadvertent criticality could occur due to the handling of special nuclear material at a commercial power reactor. The requirements of 10 CFR 70.24, therefore, are not necessary to ensure the safety of personnel during the handling of special nuclear materials at commercial power reactors.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed action and concludes that there is no significant environmental impact if the exemption is granted. Inadvertent or accidental criticality will be precluded through compliance with the Catawba Nuclear Station Technical Specifications, the design of the fuel storage racks providing geometric spacing of fuel assemblies in their storage locations, and administrative controls imposed on fuel handling procedures. Technical Specifications requirements specify reactivity limits for the fuel storage racks and minimum spacing between the fuel assemblies in the storage racks.

Appendix A of 10 CFR part 50, ''General Design Criteria for Nuclear Power Plants,'' Criterion 62, requires the criticality in the fuel storage and handling system to be prevented by physical systems or processes, preferably by use of geometrically safe configurations. This is met at Catawba, as identified in the Technical Specification Section 3.9 and in the Updated Final Safety Analysis Report (UFSAR) Section 9.1, by detailed procedures that must be available for use by refueling personnel. Therefore, as stated in the Technical Specifications, these procedures, the Technical Specifications requirements, and the design of the fuel handling equipment with built-in interlocks and safety features, provide assurance that no incident could occur during refueling operations that would result in a hazard to public health and safety. In addition, the design of the facility does not include provisions for storage of fuel in a dry location.

UFSAR Section 9.1.1, New Fuel Storage, states that new fuel will normally be stored in the spent fuel pool serving the respective unit and that it may also be stored in the fuel transfer canal. The fuel assemblies are stored in five racks in a row having a nominal center-to-center distance of 2 feet 1¾ inches. New fuel may also be stored in shipping containers. (Note that in none of these locations would criticality be possible.)

The proposed exemption would not result in any significant radiological impacts. The proposed exemption would not affect radiological plant effluents nor cause any significant occupational exposures since the Technical Specifications, design controls (including geometric spacing and design of fuel assembly storage spaces) and administrative controls preclude inadvertent criticality. The amount of radioactive waste would not be changed by the proposed exemption.

The proposed exemption does not result in any significant nonradiological environmental impacts. The proposed exemption involves features located entirely within the restricted area as defined in 10 CFR part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. As an alternative to the proposed exemption, the staff considered denial of the requested exemption. Denial of the exemption would result in no change in current environmental impacts. The environmental impacts of the proposed

action and this alternative action are similar.

Alternative Use of Resources

This exemption does not involve the use of any resources not previously considered in the Final Environmental Statement related to the Catawba Nuclear Station.

Agencies and Persons Contacted

In accordance with its stated policy, on July 7, 1997, the staff consulted with the South Carolina State official, Virgil Autrey of the Bureau of Radiological Health, South Carolina Department of Health and Environmental Control, regarding the environmental impact of the proposed exemption. The State official had no comments.

Finding of No Significant Impact

Based upon the foregoing environmental assessment, the Commission concludes that the proposed exemption will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed exemption.

For further details with respect to the proposed action, see the licensee's request for the exemption dated February 4, 1997, as supplemented by letter dated March 19, 1997, which are available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington DC, and at the local public document room located at the York County Library, 138 East Black Street, Rock Hill, South Carolina.

Dated at Rockville, Maryland, this 22nd day of July 1997.

For the Nuclear Regulatory Commission.

Herbert N. Kerkow,

Director, Project Directorate II–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 97–19933 Filed 7–28–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–244]

Rochester Gas and Electric Corporation; R. E. Ginna Nuclear Power Plant; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from certain requirements of its regulations for Facility Operating License No. DRP–18 issued to Rochester Gas and Electric Corporation (the licensee), for operation of the R. E. Ginna Nuclear Power Plant located in Wayne County, New York.

Environmental Assessment

Identification of Proposed Action

The proposed action would allow the licensee to utilize the American Society of Mechanical Engineers Boiler and Pressure Vessel Code (ASME Code) Case N–514, ''Low Temperature Overpressure Protection'' to determine its low temperature overpressure protection (LTOP) setpoints and is in accordance with the licensee's application for exemption dated June 12, 1997. The proposed action requests an exemption from certain requirements of 10 CFR 50.60, ''Acceptance Criteria for Fracture Prevention Measures for Lightwater Nuclear Power Reactors for Normal Operation,'' to allow application of an alternate methodology to determine the LTOP setpoints for the R. E. Ginna Nuclear Power Plant. The proposed alternate methodology is consistent with guidelines developed by the ASME Working Group on Operating Plant Criteria (WGOPC) to define pressure limits during LTOP events that avoid certain unnecessary operational restrictions, provide adequate margins against failure of the reactor pressure vessel, and reduce the potential for unnecessary activation of pressure relieving devices used for LTOP. These guidelines have been incorporated into Code Case N–514, ''Low Temperature Overpressure Protection,'' which has been incorporated into Appendix G of Section XI of the ASME Code and published in the 1993 Addenda to Section XI. However, 10 CFR 50.55a, ''Codes and Standards,'' and Regulatory Guide 1.147, ''Inservice Inspection Code Case Acceptability'' have not been updated to reflect the acceptability of Code Case N–514.

The philosophy used to develop Code Case N–514 guidelines is to ensure that the LTOP limits are still below the pressure/temperature (P/T) limits for normal operation, but allow the pressure that may occur with activation of pressure relieving devices to exceed the P/T limits, provided acceptable margins are maintained during these events. This philosophy protects the pressure vessel from LTOP events, and still maintains the Technical Specifications P/T limits applicable for normal heatup and cooldown in accordance with 10 CFR part 50, Appendix G and Sections III and XI of the ASME Code.

The Need for the Proposed Action

Pursuant to 10 CFR 50.60, all lightwater nuclear power reactors must meet the fracture toughness requirements for the reactor coolant pressure boundary as set forth in 10 CFR part 50, Appendix G. Appendix G of 10 CFR part 50 defines P/T limits during any condition of normal operation including anticipated operational occurrences and system hydrostatic tests, to which the pressure boundary may be subjected over its service lifetime. It is specified in 10 CFR 50.60(b) that alternatives to the described requirements in 10 CFR part 50, Appendix G, may be used when an exemption is granted by the Commission under 10 CFR 50.12.

To prevent transients that would produce excursions exceeding the 10 CFR part 50, Appendix G, P/T limits while the reactor is operating at low temperatures, the licensee installed an LTOP system. The LTOP system includes pressure relieving devices in the form of power-operated relief valves (PORVs) that are set at a pressure below the LTOP enabling temperature that would prevent the pressure in the reactor vessel from exceeding the P/T limits of 10 CFR Part 50, Appendix G. To prevent these valves from lifting as a result of normal operating pressure surges (e.g., reactor coolant pump (RCP) starting and shifting operating charging pumps) with the reactor coolant system in a solid water condition, the operating pressure must be maintained below the PORV setpoint.

In addition, to prevent damage to RCP seals, the operator must maintain a minimum differential pressure across the RCP seals. Hence, the licensee must operate the plant in a pressure window that is defined as the difference between the minimum required pressure to start a RCP and the operating margin to prevent lifting of the PORVs due to normal operating pressure surges. 10 CFR part 50, Appendix G, safety margin adds instrument uncertainty in the LTOP setpoint. The licensee's current LTOP analysis indicates that using this 10 CFR part 50, Appendix G, safety margin to determine the PORV setpoint would result in an operating window between the LTOP setpoint and the minimum pressure required for RCP seals which is significantly restricted when physical conditions such as PORV overshoot, RCP ΔPs, and static head corrections are taken into account in setpoint determination. Operating with these limits could result in the lifting of the PORVs or damage to the RCP seals during normal operation. Using Code Case N–514 would allow the licensee to

recapture most of the operating margin that is lost by factoring in the instrument uncertainties in the determination of the LTOP setpoint. The net effect of using Code Case N–514 is that the setpoint will not change significantly with the next setpoint analysis. Therefore, the licensee proposed that in determining the setpoint for LTOP events for Ginna, the allowable pressure be determined using the safety margins developed in an alternate methodology in lieu of the safety margins required by 10 CFR part 50, Appendix G. The alternate methodology is consistent with the ASME Code Case N–514. The content of this Code Case had been incorporated into Appendix G of Section XI of the ASME Code and published in the 1993 Addenda to Section XI.

An exemption from 10 CFR 50.60 is required to use the alternate methodology for calculating the maximum allowable pressure for LTOP considerations. By application dated June 12, 1997, the licensee requested an exemption from 10 CFR 50.60 to allow it to utilize the alternate methodology of Code Case N–514 to compute its LTOP setpoints.

Environmental Impacts of the Proposed Action

Appendix G of the ASME Code requires that the P/T limits be calculated: (a) using a safety factor of two on the principal membrane (pressure) stresses, (b) assuming a flaw at the surface with a depth of one quarter (¼) of the vessel wall thickness and a length of six (6) times its depth, and (c) using a conservative fracture toughness curve that is based on the lower bound of static, dynamic, and crack arrest fracture toughness tests on material similar to the Ginna reactor vessel material.

In determining the PORV setpoint for LTOP events, the licensee proposed the use of safety margins based on an alternate methodology consistent with the proposed ASME Code Case N–514 guidelines. ASME Code Case N–514 allows determination of the setpoint for LTOP events such that the maximum pressure in the vessel will not exceed 110% of the P/T limits of the existing ASME Appendix G. This results in a safety factor of 1.8 on the principal membrane stresses. All other factors, including assumed flaw size and fracture toughness, remain the same. Although this methodology would reduce the safety factor on the principal membrane stresses, use of the proposed criteria will provide adequate margins of safety to the reactor vessel during LTOP transients.

The change will not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action does involve features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. As an alternative to the proposed action, the staff considered denial of the proposed action. Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the ''Final Environmental Statement For the R. E. Ginna Nuclear Power Plant'' dated December 1975.

Agencies and Persons Consulted

In accordance with its stated policy, on July 2, 1997, the staff consulted with the Mr. Jack Spath of the New York State Energy Research and Development Authority, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated June 12, 1997, which is available for public inspection at the Commission's Public Document Room, which is located at The Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Rochester Public Library, 115 South Avenue, Rochester, New York.

Dated at Rockville, Maryland, this 23rd day of July 1997.

For the Nuclear Regulatory Commission.

Guy S. Vissing,

Senior Project Manager, Project Directorate I–1, Division of Reactor Projects I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 97–19931 Filed 7–28–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Meeting

DATE: Weeks of July 28, August 4, 11, and 18, 1997.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of July 28

There are no meetings scheduled for the week of July 28.

Week of August 4—Tentative

Monday, August 4

2:00 p.m. Briefing by International Programs (Closed—Ex. 1)
3:00 p.m. Briefing on Investigative Matters (Closed—Ex. 5 & 7)

Wednesday, August 6

9:30 a.m. Meeting with Northeast Nuclear on Millstone (Public Meeting) Contact: Bill Travers, 301–415–1200)
2:00 p.m. Briefing on Shutdown Risk Proposed Rule for Nuclear Power Plants (Public Meeting) (Contact: Tim Collins, 301–415–2897)
3:30 p.m. Affirmation Session (Public Meeting) if needed)

Thursday, August 7

9:30 a.m. Meeting with NRC Executive Council (Public Meeting) Contact: James L. Blaha, 301–415–1703)

Week of August 11—Tentative

There are no meetings scheduled for the week of August 11.

Week of August 18—Tentative

Friday, August 22

11:30 a.m. Affirmation Session (Public Meeting) (if needed)

Note: The schedule for Commission Meetings is subject to change on short notice.

To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Bill Hill (301) 415–1661.

The NRC Commission Meeting Schedule can be found on the Internet at: http://www.nrc.gov/SECY/smj/schedule.htm.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, DC 20555 (301–415–1661).

In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to wmh@nrc.gov or dkw@nrc.gov.

Dated: July 25, 1997.

William M. Hill, Jr.,

Secy Tracking Officer, Office of the Secretary.

[FR Doc. 97–20073 Filed 7–25–97; 2:31 pm]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel No. IC–22758; 812–10626]

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Merrill Lynch Government Securities, Inc.; Notice of Application

July 22, 1997.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of application for an order under the Investment Company Act of 1940 (the ''Act'').

APPLICANTS: Merrill Lynch, Pierce, Fenner & Smith Incorporated (''Merrill Lynch'') and Merrill Lynch Government Securities, Inc. (''GSI'').

RELAVANT ACT SECTIONS: Order requested under section 12(d)(1)(J) for an exemption from section 12(d)(1), under section 6(c) for an exemption from section 14(a), and under section 17(b) for an exemption from section 17(a).

SUMMARY OF APPLICATION: Applicants request an order with respect to Structured Yield Product Exchangeable for Stock Trusts and future trusts that are substantially similar and for which Merrill Lynch will serve as a principal underwriter (the ''Trusts'') that would (a) permit other registered investment companies to own a greater percentage of the total outstanding voting stock (the ''Securities'') of any Trust than that permitted by section 12(d)(1), (b) exempt the Trusts from the initial net worth requirements of section 14(a), and (c) permit the Trusts to purchase U.S. government securities from Merrill Lynch and/or GSI at the time of a Trust's initial issuance of Securities.

FILING DATES: The application was filed on April 21, 1997, and amended on July 18, 1997.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a heari8ng by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on August 15, 1997, and should be accompanied by proof of service on applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, World Financial Center, North Tower, 250 Vesey Street, New York, New York 10281–1318.

FOR FURTHER INFORMATION CONTACT: Brian T. Hourihan, Senior Counsel, at (202) 942–05267, or Mary Kay Frech, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. Each Trust will be a limited-life, grantor trust registered under the Act as a non-diversified, closed-end management investment company. Merrill Lynch will serve as a principal underwriter (as defined in section 2(a)(29) of the Act) of the Securities issued to the public by each Trust.

2. Each Trust will, at the time of its issuance of Securities, (a) enter into one or more forward purchase contracts (the ''Contracts'') with a counterparty to purchase a formulaically-determined number of a specified equity security or securities (the ''Shares'') of one specified issuer,[1] and (b) in some cases, purchase certain U.S. Treasury securities (''Treasuries''), which may include interest-only or principal-only securities maturing at or prior to the Trust's termination. The Trusts will purchase the Contracts from counterparties that are not affiliated with either the relevant Trust or applicants. The investment objective of each Trust will be to provide to each holder of Securities (''Holder'') (a) current cash distributions from the proceeds of any Treasuries, and (b) participation in, or limited exposure to, changes in the market value of the underlying Shares.

3. In all cases, the Shares will trade in the secondary market and the issuer of the Shares will be a reporting company under the Securities Exchange Act of 1934. The number of Shares, or the value thereof, that will be delivered to a Trust pursuant to the Contracts may be fixed (*e.g.*, one Share per Security issued) or may be determined pursuant to a formula, the product of which will vary with the price of the Shares. A formula generally will result in each Holder of Securities receiving fewer Shares as the market value of such Shares increases, and more Shares as their market value decreases.[2] At the termination of each Trust, each Holder will receive the number of Shares per Security, or the value thereof, as determined by the terms of the Contracts, that is equal to the Holder's *pro rata* interest in the Shares or amount received by the Trust under the Contracts.[3]

4. Securities issued by the Trusts will be listed on a national securities exchange or trade on the National Association of Securities Dealers Automated Quotation System. Thus, the Securities will be ''national market system'' securities subject to public price quotation and trade reporting requirements. After the Securities are issued, the trading price of the Securities is expected to vary from time to time based primarily upon the price of the underlying Shares, interest rates, and other factors affecting conditions and prices in the debt and equity markets. Mrerrill Lynch currently

[1] No Trust will hold Contracts relating to the Shares of more than one issuer. (p.5, n.3)

[2] A formula is likely to limit the Holder's participation in any appreciation of the underlying Shares, and it may, in some cases, limit the Holder's exposure to any depreciation in the underlying Shares. It is anticipated that the Holders will receive a yield greater than the ordinary dividend yield on the Shares at the time of the issuance of the Securities, which is intended to compensate Holders for the limit on the Holders' participation in any appreciation of the underlying Shares. In some cases, there may be an upper limit on the value of the Shares that a Holder will ultimately receive. (p.6)

[3] The contracts may provide for an option on the part of a counterparty to deliver Shares, cash, or a combination of Shares and cash to the Trust at the terminaiton of each Trust. (p.7, n.5)

intends, but will not be obligated, to make a market in the Securities of each Trust.

5. Each Trust will be internally managed by three trustees and will not have any separate investment adviser. The trustees will have no power to vary the investments held by each Trust. A bank qualified to serve as a trustee under the Trust Indenture Act of 1939, as amended, will act as custodian for each Trust's assets and a paying agent, registrar, and transfer agent with respect to the Securities of each Trust. Such bank will have no other affiliation with, and will not be engaged in any other transaction with, any Trust. The day-to-day administration of each Trust will be carried out by Merrill Lynch or such bank.

6. The Trusts will be structured so that the trustees are not authorized to sell the Contracts or Treasuries under any circumstances. The Trusts will hold such Contracts until maturity, at which time they will be settled according to their terms. However, in the event of the bankruptcy or insolvency of any counterparty to a Contract with a Trust, the obligations of such counterparty under the Contract will be accelerated and the available proceeds thereof will be distributed to the Security Holders.

7. The trustees of each Trust will be selected initially by Merrill Lynch, together with any other initial Holders, or by the grantors of such Trust. The Holders of each Trust will have the right, upon the declaration in writing or vote of more than two-thirds of the outstanding Securities of the Trust, to remove a trustee. Holders will be entitled to a full vote for each Security held on all matters to be voted on by Holders and will not be able to cumulate their votes in the election of trustees. The investment objectives and policies of each Trust may be changed only with the approval of a ''majority of the Trust's outstanding Securities'' [4] or any greater number required by the Trust's constituent documents. Unless Holders so request, it is not expected that the Trusts will hold any meetings of Holders, or that Holders will ever vote.

8. The Trusts will not be entitled to any rights with respect to the Shares until any Contracts requiring delivery of the Shares to the Trust are settled, at which the Shares will be promptly distributed to Holders. The Holders, therefore, will not be entitled to any rights with respect to the Shares (including voting rights or the right to receive any dividends or other distributions in respect thereof) until receipt by them of the Shares at the time the Trust is liquidated.

9. Each Trust will be structed so that its organizational and ongoing expenses will not be borne by the Holders, but rather, directly or indirectly, by Merrill Lynch, the counterparties, or another third party, as will be described in the prospectus for the relevant Trust. At the time of the original issuance of the Securities of any Trust, there will be paid to each of the administrator, the custodian, and the paying agent, and to each trustee, a one-time amount in respect of such agent's fee over its term. Any expenses of the Trust in excess of this anticipated amount will be paid as incurred by a party other than the Trust itself (which party may be Merrill Lynch).

Applicants' Legal Analysis

A. Section 12(d)(1)

1. Section 12(d)(1)(A)(i) of the Act prohibits any registered investment company from owning more than 3% of the total outstanding voting stock of any other investment company. Section 12(d)(1)(C) of the Act similarly prohibits any investment company, other investment companies having the same investment adviser, and companies controlled by such investment companies from owning more than 10% of the total outstanding voting stock of any closed-end investment company.

2. Section 12(d)(1)(J) of the Act provides that the SEC may exempt persons or transactions from any provision of section 12(d)(1), if, and to the extent that, such exemption is consistent with the public interest and protection of investors.

3. Applicants believe, in order for the Trust to be marketed most successfully, and to be traded at a price that most accurately reflects their value, that it is necessary for the Securities of each Trust to be offered to large investment companies and investment company complexes. Applicants state that large investment companies and investment company complexes seek to spread the fixed costs of analyzing specific investment opportunities by making sizable investments in those opportunities that prove attractive. Conversely, it may not be economically rational for such investors, or their advisers, to take the time to review an investment opportunity if the amount that they would ultimately be permitted to purchase is immaterial in light of the total assets of the investment company or investment company complex. Therefore, applicants argue that, in order for the Trusts to be economically attractive to large investment companies and investments company complexes, such investors must be able to acquire Securities in each Trust in excess of the limitations imposed by sections 12(d)(1)(A)(i) and 12(d)(1)(C). Applicants request that the SEC issue an order under section 12(d)(1)(J) exempting the Trusts from such limitations.

4. Applicants state that section 12(d)(1) was enacted in order to prevent one investment company from buying control of other investment companies and creating complicated pyramidal structures. Applicants also state that section 12(d)(1) was intended to address two principal categories of problems: those associated with the ''pyramiding'' of control over portfolio funds by fund-holding companies and the layering-on of costs to investors.

5. The pyramiding concerns fall into two categories. One arises from the potential for undue influence resulting from the pyramiding of voting control of the acquired investment company. Applicants believe that this concern generally does not arise in the case of the Trusts because neither the trustees nor the Holders will have the power to vary the investments held by each Trust or to acquire or dispose of the assets of the Trusts. To the extent that Holders can change the composition of the board of trustees or the fundamental policies of each Trust by vote, applicants argue that any concerns regarding undue influence will be eliminated by including a provision in the charter documents for the Trusts that will require that any investment companies owning voting stock of any trust in excess of the limits imposed by sections 12(d)(1)(A)(i) and 12(d)(1)(C) will vote their Securities in proportion to the votes of all other Holders.

6. The second concern with respect to pyramiding is that an acquiring investment company might be able to influence unduly the persons operating the acquired investment fund. This undue influence could arise through a threat to redeem assets invested in the underlying fund at a time, or in a manner, which is disadvantageous to that fund, or to threaten to vote shares in that fund in a manner inconsistent with the best interests of that fund and its shareholders. Applicants believe that this concern does not arise in the case of the Trusts because the Securities will not be redeemable and because the trustees' management control will be so limited.

[4] A ''majority of the Trust's outstanding Securities'' means the lesser of (a) 67% of the Securities represented at a meeting at which more than 50% of the outstanding Securities are represented, and (b) more than 50% of the outstanding Securities. (p. 10)

7. The second major objective of section 12(d)(1) is to avoid imposing on investors the excessive costs and fees that may result from multiple layers of investments. Excessive costs can result from investors paying double sales charges when purchasing shares of a fund which, in turn, invests in other funds, or from duplicative expenses arising from the operation of two funds in place of one. Applicants believe that neither of these concerns arises in the case of the Trusts because of the limited on-going fees and expenses incurred by the Trusts and the fact that generally such fees and expenses will be borne, directly or indirectly, by Merrill Lynch or another third party, not by the Holders. In addition, the Holders will not, as a practical matter, bear the organizational expenses (including underwriting expenses) of the Trusts. Applicants assert that such organizational expenses effectively will be borne by the counterparties in the form of a discount in the price paid to them for the Contracts, or will be borne directly by Merrill Lynch, the counterparties, or other third parties. Thus, a Holder will not pay duplicative charges to purchase its investment in any Trust. Finally, there will be no duplication of advisory fees because the Trusts will be internally managed by their trustees.

8. Applicants believe that the investment product offered by the Trusts serves a valid business purpose. The Trusts, unlike most registered investment companies, are not marketed to provide investors with either professional investment asset management or the benefits of investment in a diversified pool of assets. Rather, applicants assert that the Securities are intended to provide Holders with a security having unique payment and risk characteristics, including an anticipated higher yield than the ordinary dividend yield on the Shares at the time of the issuance of the Securities.

9. Applicants believe that the purposes and policies of the section 12(d)(1) are not implicated by the Trusts and that the requested exemption from section 12(d)(1) is consistent with the public interest and the protection of investors.

B. Section 14(a)

1. Section 14(a) of the Act requires, in pertinent part, that an investment company have a net worth of at least $100,000 before making any public offering of its shares. The purpose of section 14(a) is to ensure that investment companies are adequately capitalized prior to or simultaneously with the sale of their securities to the public. Rule 14a–3 exempts from section 14(a) unit investment trusts that meet certain conditions in recognition of the fact that, once the units are sold, a unit investment trust requires much less commitment on the part of the sponsor than does a management investment company.

2. Applicants argue that, while the Trusts are classified as management companies, they have the characteristics of unit investment trusts that are relevant to the rule 14a–3 exemption. Rule 14a–3 provides that a unit investment trust investing in eligible trust securities shall be exempt from the net worth requirement, provided that the trust holds at least $100,000 of eligible trust securities at the commencement of a public offering. Investors in the Trusts, like investors in a traditional unit investment trust, will not be purchasing interests in a managed pool of securities, but rather in a fixed and disclosed portfolio that is held until maturity. Applicants believe that the make-up of each Trust's assets, therefore, will be ''locked-in'' for the life of the portfolio, and there is no need for an ongoing commitment on the part of the underwriter.

3. Applicants state that, in order to ensure that each Trust will become a going concern, the Securities of each Trust will be publicly offered in a firm commitment underwriting, registered under the Securities Act of 1933, and resulting in net proceeds to each Trust of at least $10,000,000. Prior to the issuance and delivery of the Securities of each Trust to the underwriters, the underwriters will enter into an underwriting agreement pursuant to which they will agree to purchase the Securities subject to customary conditions to closing. The underwriters will not be entitled to purchase less than all of the Securities of each Trust. Accordingly, applicants state that either the offering will not be completed at all or each Trust will have a net worth substantially in excess of $100,000 on the date of the issuance of the Securities. Applicants also do not anticipate that the net worth of the Trusts will fall below $100,000 before they are terminated.

4. Section 6(c) of the Act provides that the SEC may exempt persons or transactions if, and to the extent that, such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request that the SEC issue an order under section 6(c) exempting the Trusts from any requirements of section 14(a). Applicants believe that such exemption is appropriate in the public interest and consistent with the protection of investors and the policies and provisions of the Act.

C. Section 17(a)

1. Sections 17(a)(1) and 17(a)(2) of the Act generally prohibit the principal underwriter, or any affiliated person of the principal underwriter, of any investment company from selling or purchasing any securities to or from that investment company. The result of these provisions is to preclude the Trusts from purchasing Treasuries from Merrill Lynch and/or GSI.

2. Section 17(b) of the Act provides that the SEC shall exempt a proposed transaction from section 17(a) if evidence establishes that: (a) the terms of the proposed transaction are reasonable and fair and do not involve overreaching; (b) the proposed transaction is consistent with the policies of the registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) to permit the Trusts to purchase Treasures from the applicants.

3. Applicants state that the policy rationale underlying section 17(a) is the concern that an affiliated person of an investment company, by virtue of such relationship, could cause an investment company to purchase securities of poor quality from the affiliated person or to overpay for any securities. Applicants argue that it is unlikely that Merrill Lynch or GSI would be able to exercise any adverse influence over the Trusts with respect to purchases of Treasuries because Treasuries do not vary in quality and are traded in one of the most liquid markets in the world. Treasuries are available through both primary and secondary dealers, making the Treasury market very competitive. In addition, market prices on Treasuries can be confirmed on a number of commercially available information screens. Applicants argue that because GSI is one of a limited number of primary dealers in Treasuries, the applicants will be able to offer the Trusts prompt execution of their Treasury purchases at very competitive prices.

4. Applicants state that they are only seeking relief from section 17(a) with respect to the initial purchase of the Treasuries and not with respect to an on-going course of business. Consequently, investors will know before they purchase a Trust's Securities the Treasuries that will be owned by the

Trust and the amount of the case payments that will be provided periodically by the Treasuries to the Trust and distributed to Holders. Applicants also assert that whatever risk there is of overpricing the Treasuries will be borne by the counterparts and not by the Holders because the costs of the Treasuries will be calculated into the amount paid on the Contracts. Applicants argue that, for this reason, the counterparties will have a strong incentive to monitor the price paid for the Treasuries, because any overpayment could result in a reduction in the amount that they would be paid on the Contracts.

5. Applicants believe that the terms of the proposed transaction are reasonable and fair and do not involve overreaching on the part of any person, that the proposed transaction is consistent with the policy of each of the Trusts, and that the requested exemption is appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policies and provisions of the Act.

Applicants' Conditions

Applicants agree that the order granting the requested relief will be subject to the following conditions:

1. Any investment company owning voting stock of any Trust in excess of the limits imposed by section 12(d)(1) of the Act will be required by the Trust's charter documents to vote its Trust shares in proportion to the vote of all other Holders.

2. The trustees of each Trust, including a majority of the trustees who are not interested persons of the Trust, (a) Will adopt procedures that are reasonably designed to provide that the conditions set forth below have been complied with; (b) will make and approve such changes as deemed necessary; and (c) will determine that the transactions made pursuant to the order were effected in compliance with such procedures.

3. The Trusts (a) Will maintain and preserve in an easily accessible place a written copy of the procedures (and any modifications thereto), and (b) will maintain and preserve for the longer of (i) the life of the Trusts and (ii) six years following the purchase of any Treasuries, the first two years in an easily accessible place, a written record of all Treasuries purchased, whether or not from Merrill Lynch or GSI, setting forth a description of the Treasuries purchased, the identity of the seller, the terms of the purchase, and the information or materials upon which the determinations described below were made.

4. The Treasuries to be purchased by each Trust will be sufficient to provide payments to Holders of Securities that are consistent with the investment objectives and policies of the Trust as recited in the Trust's registration statement and will be consistent with the interests of the Trust and the Holders of its Securities.

5. The terms of the transactions will be reasonable and fair to the Holders of the Securities issued by each Trust and will not involve overreaching of the Trust or the Holders of Securities thereof on the part of any person concerned.

6. The fee, spread, or other remuneration to be received by Merrill Lynch and/or GSI will be reasonable and fair compared to the fee, spread, or other remuneration received by dealers in connection with comparable transactions at such time, and will comply with section 17(e)(2)(C) of the Act.

7. Before any Treasuries are purchased by the Trust, the Trust must obtain such available market information as it deems necessary to determine that the price to be paid for, and the terms of the transaction is at least as favorable as that available from other sources. This shall include the Trust obtaining and documenting the competitive indications with respect to the specific proposed transaction from two other independent government securities dealers. Competitive quotation information must include price and settlement terms. These dealers must be those who, in the experience of the Trust's trustees, have demonstrated the consistent ability to provide professional execution of Treasury transactions at competitive market prices. They also must be those who are in a position to quote favorable prices.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 97–19836 Filed 7–28–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–22759; 811–8742]

Pacifica Variable Trust; Notice of Application

July 23, 1997.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the ''Act'').

APPLICANT: Pacifica Variable Trust.

RELEVANT ACT SECTION: Section 8(f)

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATES: The application was filed on January 31, 1997, and amendments thereto were filed on May 6, 1997, and June 19, 1997.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on August 18, 1997, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicant, 237 Park Avenue, Suite 910, New York, NY 10017.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Staff Attorney, at (202) 942–0574, or H.R. Hallock, Jr., Special Counsel, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is an open-end management investment company that is organized as a Delaware business trust. On August 30, 1994, applicant registered under the Act and filed a registration statement pursuant to section 8(b) of the Act on Form N–1A to register an indefinite number of

shares for each of its five portfolios. The registration statement became effective on December 1, 1995, and applicant commenced a public offering of its shares on January 2, 1996. Applicant's shares were offered only to separate accounts funding variable annuity contracts issued by Anchor National Life Insurance Company.

2. At a meeting of applicant's board of trustees on August 15, 1996, the board unanimously approved the deregistration and dissolution of applicant. Applicant states it did not seek securityholder authorization for its deregistration and dissolution because the sole shareholder of each of its series voluntarily redeemed its shares.

3. On September 26, 1996, applicant's liquidation date, applicant's sole shareholder of each of applicant's series voluntarily redeemed its shares at net asset value. The number of securities redeemed and the aggregate net asset value attributable to each portfolio were as follows: (a) The Balanced Portfolio redeemed 259,699.737 shares with an aggregate net asset value of $2,708,148.86; (b) the Emerging Growth Portfolio redeemed 262,809.167 shares with an aggregate net asset value of $2,763,438.40; (c) the Equity Value Portfolio redeemed 261,410.613 shares with an aggregate net asset value of $2,821,404.74; (d) the Intermediate Bond Portfolio redeemed 258,378.579 shares with an aggregate net asset value of $2,487,152.20; and (e) the Money Market Portfolio redeemed 2,587,773.76 shares with an aggregate net asset value of $2,587,773.76. There are no securityholders of applicant to whom distributions in complete liquidation of their interests have not been made.

4. The expenses incurred in connection with applicant's liquidation were approximately $14,344.59. The expenses were assumed by Wells Fargo Bank, the parent company of applicant's investment adviser. Prior to applicant's liquidation date, all of applicant's portfolio securities and other assets were disposed of in arm's length transactions at fair market value. Applicant paid ordinary and reasonable brokerage commissions in connection with such transactions.

5. Applicant has no securityholders or assets. Applicant has no outstanding debts or liabilities. Applicant is not a party to any litigation or administrative proceeding.

6. Applicant is not now engaged, nor does it propose to engage, in any business activities other than those necessary for the winding up of its affairs. Applicant will file a certificate of cancellation with the State of Delaware to effect its dissolution.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 97–19905 Filed 7–28–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–38861; File No. SR–Amex–97–23]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by American Stock Exchange, Inc. Relating to Updates to a Qualification Examination Administered by the Exchange

July 22, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] notice is hereby given that on June 20, 1997, the American Stock Exchange, Inc. (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing an updated version of the contents of the Listed Put and Call Option Questionnaire for Registered Personnel.[2] The text of the proposed rule change is available at the Office of the Secretary, the Amex and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. § 78s(b)(1).

[2] This examination was previously referred to as the Put and Call Option Questionnaire for Listed Personnel.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing an updated version of the contents of the Listed Put and Call Option Questionnaire for Registered Personnel.[3] This examination must be successfully completed by a member or registered employee who was registered and approved by the Exchange prior to 1977,[4] and now wishes to engage in a public options business.[5] The examination is administered by the broker-dealer member organization with which the individual is associated, which then certifies to the Exchange that the applicant has satisfactorily completed the examination.

The proposed rule change is consistent with Section 6(b) of the Act, in general, and Section 6(b)(5), in particular, in that it is designed to protect investors and the public interest by helping to assure member competence. In addition, the proposed rule change is consistent with Section 6(c)(3)(A) in that it is designed to examine the training, experience and competence of applicants for both AMEX membership and verify such applicant qualifications for Exchange membership.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory

[3] This examination was previously referred to as the Put and Call Option Questionnaire for Listed Personnel.

[4] The Series 7 began covering the subject of standardized options in 1977.

[5] *See* Exchange Rule 920.

organization consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying the Commission's Public Reference Room in Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to the file number in the caption above and should be submitted by August 19, 1997.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 97–19835 Filed 7–28–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–38859; File No. SR–Amex–97–22]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange, Inc. Relating to Revised Options Fee Schedule

July 22, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on June 18, 1997, the American Stock Exchange, Inc. (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The American Stock Exchange has revised its schedule of charges imposed on trades in options executed on the Exchange. The text of the fee change is available at the Office of the Secretary, the Amex and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange currently imposes a transaction charge on options trades executed on the Exchange, with the charge varying depending on whether it is an equity or index option and then on whether it was executed for a specialist or market maker, for a member firm's proprietary account, or for a customer. The Exchange also imposes a charge for clearance of options trades, as well as an options floor brokerage charge which again varies like the above transaction charge depending on whom the trade was executed for.

The Exchange has revised its schedule of options charges to impose caps on the number of options contracts subject to Exchange option charges. Options charges will be imposed on customer trades for the first 2,000 contracts and on member firm proprietary, specialist, and market maker trades for the first 3,000 contracts. The caps will apply to all three options charges—transaction, options clearance, and options floor brokerage and will apply to one day's trades of 100 or more contracts per execution on one side of any series executed by one specialist/trader/broker (for one member firm) and cleared by one clearing firm. Trades of less than 100 contracts that are multiple contra parties to trades of 100 or more contracts will also be added to the total number of contracts subject to the cap. The same fee schedule and cap provision will apply to standardized and FLEX options. The special fee schedule on box transactions is also being repealed in the expectation that the proposed caps will be more attractive to the users of boxes than the special box schedule. The Exchange believes that the changes are necessary in order to make the Exchange's option fee schedule more competitive with costs of trading other financial instruments and to increase the number of options orders that are routed to the Exchange.

The Exchange's schedule of options charges, as revised above, has been submitted as Exhibit A to the submitted filing. The revised options fee schedule has been implemented starting with transactions effected on and after June 2, 1997.[2]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act[3] in general and furthers the objectives of Section 6(b)(4)[4] in particular in that it provides for the equitable allocation of reasonable dues, fees, and other charges among the Exchange's members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[1] 15 U.S.C. 78s(b)(1).

[2] According to the Amex, the retroactive application of the proposed fee schedule will allow the Exchange to apply a single fee schedule to transactions effected in June, thereby allowing the Exchange to avoid the administrative billing burden inherent in applying one fee schedule to the first half of the month of June and another fee schedule to the latter half of the month. Telephone conversation between J. Bruce Ferguson, Associate General Counsel, Legal & Regulatory Policy, and George A. Villasana, Division of Market Regulation (''Division''), SEC, on July 16, 1997. *See also* letter from J. Bruce Ferguson, Associate General Counsel, Legal & Regulatory Policy, to George A. Villasana, Attorney, Division, SEC, dated July 17, 1997. The Amex stated that members were notified of the proposed fee change via Amex Information Circular 97–0535 and that the proposal would not result in increased fees for any members. *Id.*

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(4).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes or changes a due, fee, or other charge imposed by the Exchange and, therefore, has become effective pursuant to Section 19(b)(3)(A) of the Act [5] and subparagraph (e) of rule 19b–4 thereunder.[6]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other that those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the American Stock Exchange. All submissions should refer to File No. SR–Amex–97–22 and should be submitted by [insert date 21 days from date of publication].

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4.

[7] 17 CFR 200.30–3(a)(12).

Jonathan G. Katz,

Secretary.

[FR Doc. 97–19837 Filed 7–28–97; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new, and/or currently approved information collection.

DATES: Comments should be submitted on or before September 29, 1997.

FOR FURTHER INFORMATION CONTACT: Curtis B. Rich, Management Analyst, Small Business Administration, 409 3rd Street, S.W., Suite 5000, Washington, D.C. 20416. Phone Number: 202–205–6629.

SUPPLEMENTARY INFORMATION:

Title: ''Customer Survey''.
Type of Request: New Collection.
Form No: N/A.
Description of Respondents: Participating SBA Lenders and Participants in SBA Programs.
Annual Responses: 13,800.
Annual Burden: 2,300.
Comments: Send all comments regarding this information collection to Patricia Holden, Management Analyst, Office of Field Operations, Small Business Administration, 409 3rd Street, S.W., Suite 7125, Washington, D.C. 20416. Phone No: 202–205–6385. Send comments regarding whether this information collection is necessary for the proper performance of the function of the agency, accuracy of burden estimate, in addition to ways to minimize this estimate, and ways to enhance the quality.

Dated: July 22, 1997.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 97–19895 Filed 7–28–97; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #2968]

State of Minnesota

Ramsey County and the contiguous Counties of Anoka, Dakota, Hennepin, and Washington in the State of Minnesota constitute a disaster area as a result of damages caused by severe storms, flash flooding, and sewer backup which occurred on July 1–17, 1997. Applications for loans for physical damages may be filed until the close of business on September 18, 1997 and for economic injury until the close of business on April 20, 1998 at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308.

The interest rates are:

	percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	8.000
Homeowners Without Credit Available Elsewhere	4.000
Businesses With Credit Available Elsewhere	8.000
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000
Others (Including Non-Profit Organizations) With Credit Available Elsewhere	7.250
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 296806 and for economic injury the number is 953700.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: July 18, 1997.

Aida Alvarez,

Administrator.

[FR Doc. 97–19824 Filed 7–28–97; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #2962]

State of Texas

Amendment #1

In accordance with notices from the Federal Emergency Management Agency dated July 15, 16, and 18, 1997, the above-numbered Declaration is hereby amended to include the Counties of Blanco, Comal, Eastland, Edwards, and Hays in the State of Texas as a disaster area due to damages caused by severe thunderstorms and flooding. This declaration is further amended to establish the incident period for this disaster as beginning on June 21, 1997 and continuing through July 15, 1997.

In addition, applications for economic injury loans from small businesses located in the following contiguous

counties in the State of Texas may be filed until the specified date at the previously designated location: Brown, Callahan, Comanche, Erath, Palo Pinto, Shackelford, Stevens, Sutton, and Val Verde.

All other information remains the same, i.e., the deadline for filing applications for physical damage is September 5, 1997 and for economic injury the termination date is April 7, 1998.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: July 21, 1997.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 97–19825 Filed 7–28–97; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Privacy Act of 1974, As Amended; Computer Matching Program (SSA/Railroad Retirement Board (RRB)—SSA Match Number 1007)

AGENCY: Social Security Administration (SSA).

ACTION: Notice of Computer Matching Program.

SUMMARY: In accordance with the provisions of the Privacy Act, this notice announces a computer matching program that SSA plans to conduct with RRB.

DATES: SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform and Oversight of the House of Representatives and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by either telefax to (410) 966–5138, or writing to the Associate Commissioner for the Office of Program Support, 4400 West High Rise Building, 6401 Security Boulevard, Baltimore, MD 21235. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: The Associate Commissioner for the Office of Program Support as shown above.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503), amended the Privacy Act (5 U.S.C. 552a) by establishing conditions under which computer matching involving the Federal government could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508), further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. Among other things, it requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain Data Integrity Board approval of the match agreements;

(3) Furnish detailed reports about matching programs to Congress and OMB;

(4) Notify applicants and beneficiaries that their records are subject to matching; and

(5) Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: July 15, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

Notice of Computer Matching Program, Railroad Retirement Board (RRB) With Social Security Administration (SSA)

A. Participating Agencies

SSA and RRB.

B. Purpose of the Matching Program

To identify social security beneficiaries and applicants who have railroad earnings which must be considered wages under the Social Security Act for purposes of determining individual entitlement and monthly benefit amounts for Social Security Retirement, Survivors and Disability Insurance under title II of the Social Security Act. Earnings considered compensation under the Railroad Retirement Act instead must be considered wages under the Social Security Act. This situation applies if the numberholder has less than 10 years of railroad service or has 10 or more years of service but does not have a current connection with the railroad industry at the time of his or her death.

C. Authority for Conducting the Matching Program

Sections 202, 205(o) and 215(f) of the Social Security Act (42 U.S.C. 402, 405(o) and 415(f)) and section 18 of the Railroad Retirement Act (45 U.S.C. 231(q)(2)).

D. Categories of Records and Individuals Covered by the Match

The RRB will provide SSA with an electronic data file containing earnings information from RRB's Service and Compensation Record (SCORE) file. The complete name of the SCORE file is RRB–5 Master File of Railroad Employees' Creditable Compensation—RRB. SSA will then match the RRB data with records maintained on social security beneficiaries and applicants in its Master Beneficiary Record (MBR), SSA/OSR, 09–60–0090 and Master Earnings File (MEF), SSA/OSR, 09–60–0059.

E. Inclusive Dates of the Match

The matching program shall become effective no sooner than 40 days after notice of the matching program is sent to Congress and the Office of Management and Budget (OMB), or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 97–19827 Filed 7–28–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements Agency Information Collection Activity Under OMB Review

AGENCY: Office of the Secretary, DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of

information was published March 28, 1997 [62 FR 14967].

DATES: Comments must be submitted on or before August 28, 1997.

FOR FURTHER INFORMATION CONTACT: Complete copies of each request for collection of information may be obtained at no charge from Mr. Edward Kosek, NHTSA Information Collection Clearance Officer, NHTSA, 400 Seventh Street, SW., Room 6123, Washington, DC 20590. Mr. Kosek's telephone number is (202) 366–2590. Please identify the relevant collection of information by referring to its OMB Clearance Number.

SUPPLEMENTARY INFORMATION:

National Highway Traffic Safety Administration

Title: National Driver Register Reporting Requirement for 23 CFR part 1327.

Type of Request: Reinstatement, with change, of a previously approved collection for which approval has expired.

Form Number: N/A.

OMB Control Number: 2127–0001.

Affected Public: The 51 respondents are the State driver licensing agencies, including the District of Columbia.

Abstract: The National Driver Register Act of 1982 (Pub.L. 97–364), as amended, mandates the Secretary of Transportation to establish and maintain a National Driver Register to assist chief driver licensing officials of participating states in exchanging information about the motor vehicle driving records of individuals. The Act requires the chief driver licensing official of each participating state to submit a report to the Secretary of each individual who is denied a motor vehicle operator's license by that State for cause; whose motor vehicle operator's license is revoked, suspended, or canceled by that State for cause; or who is convicted under the laws of that State of any of the following motor vehicle-related offenses or comparable offenses: (a) Operating a motor vehicle while under the influence of, or impaired by, alcohol or a controlled substance; (b) a traffic violation arising in connection with a fatal traffic accident, reckless driving, or racing on the highways; (c) failing to give aid or provide identification when involved in an accident resulting in death or personal injury; (d) perjury or knowingly making a false affidavit or statement to officials about activities governed by a law or regulation on the operation of a motor vehicle. The Act also requires the chief driver licensing officials of participating states to check the NDR on all first time above-minimum age driver license applicants in their states.

The Commercial Motor Vehicle Safety Act of 1986 requires the states to check the NDR for all applicants for Commercial Drivers Licenses.

Description of the need for the information and proposed use of the information—The purpose of the NDR, and thus this information collection activity, is to prevent the issuance of driver's licenses to problem drivers in order to enhance traffic safety. Through amendments to the NDR Act, the activity also serves to prevent the certification of airline pilots, merchant mariners, locomotive operators, and individuals employed as motor vehicle operators if they are problem drivers.

The information will be used by NHTSA in exercising its statutory authority to operate the NDR. Without this information, states could issue licenses to individuals who are suspended or revoked in other states, or could issue a duplicate license to an individual who is licensed in another state allowing them to spread their violations over a number of licenses.

Annual Estimated Burden: 1977 burden hours.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW., Washington, DC 20503, Attention NHTSA Desk Officer.

Comments are Invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Departments estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on July 27, 1997.

Phillip A. Leach,

Clearance Officer, United States Department of Transportation.

[FR Doc. 97–19951 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: Office of the Secretary, DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act 1995 (44 U.S.C. Chapter 35), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on November 22, 1996 [61 FR 59484].

SUPPLEMENTARY INFORMATION:

Federal Highway Administration

DATES: Comments must be submitted on or before August 28, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. David R. Miller, Office of Motor Carrier Research and Standards, (202) 366–4009, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

Title: Controlled Substances and Alcohol Testing.

OMB Number: 2125–0543.

Type Request: Reinstatement, with change, of a previously approved collection for which approval has expired.

Form(s): FHWA: MCS–154, FHWA: MCS–155, OMB No: 9999–0023, OMB no: 2105–0529

Affected Public: 553,238 motor carriers.

Abstract: Title 49 U.S.C. 31306 requires the Secretary of Transportation to promulgate regulations that require motor carriers to test their drivers for the use of alcohol and controlled substances. The Secretary has adopted regulations that require commercial motor vehicle (CMV) drivers to submit to testing by motor carriers.

The information collection is required for motor carriers to document compliance with the controlled substances and alcohol testing regulations, show driver's Constitutional rights andprivacy are sufficiently protected, show that drug-positive drivers and drivers with any

alcohol concentration of 0.02 or greater in their body, are not being used to operate CMVs on public roads, and show that drivers who have tested positive have received necessary assistance in resolving their use problem. The records are used by the FHWA, and its State and local partners in the Motor Carrier Safety Assistance Program, to determine whether drivers have driven CMVs while using alcohol and drugs in violation of the law.

Estimated Total Annual Burden: 2,309,703 hours.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW., Washington, DC 20503, Attention FHWA Desk Officer.

Interested parties are invited to send comments regarding any aspect of this collection of information, including, but not limited to: whether the proposed collection of information isnecessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on July 23,1997.

Phillip A. Leach,

Clearance Officer, United States Department of Transportation.

[FR Doc. 97–19952 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Executive Committee of the Aviation Rulemaking Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Executive Committee of the Federal Aviation Administration Aviation Rulemaking Advisory Committee.

DATES: The meeting will be held on August 13, 1997, at 10 a.m. Arrange for oral presentations by August 1, 1997.

ADDRESSES: The meeting will be held at the Aerospace Industries Association of America, 1250 Eye Street, NW., Wright Room, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Miss Jean Casciano, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–9683; fax (202) 267–5075; e-mail Jean.Casciano@faa.dot.gov..

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II), notice is hereby given of a meeting of the Executive Committee to be held on August 13, 1997, at the Aerospace Industries Association of America, 1250 Eye Street, NW., Wright Room, Washington, DC, 10 a.m. The agenda will include:.

- A status report from the Digital Information Working Group, including a possible vote on a proposed electronic access NPRM
- Update on the status of the effort to define a strategy for expediting the completion of old ARAC tasks and recommendations
- Update on the status of the Overflights of the National Parks effort
- Administrative issues

Attendance is open to the interested public but will be limited to the space available. The public must make arrangements by August 1, 1997, to present oral statements at the meeting. The public may present written statements to the executive committee at any time by providing 25 copies to the Executive Director, or by bringing the copies to him at the meeting.

Sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in Washington, DC, on July 22, 1997.

Joseph A. Hawkins,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. 97–19857 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application (97–04–C–00–JFK) to Impose and Use the Revenue From a Passenger Facility Charge (PFC) at John F. Kennedy International Airport (JFK), Jamaica, NY; LaGuardia Airport (LGA), Flushing, NY and Newark NJ International (EWR), Newark, NJ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at JFK, LGA, EWR under the provisions of 49 U.S.C. § 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before August 28, 1997.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Mr. Philip Brito, Manager, New York Airports District Office, 600 Old County Road, Suite 446, Garden City, New York 11530.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Anthony G. Cracchiolo, Director of New York Airport Access Program, for the Port Authority of New York & New Jersey at the following address: The Port Authority of New York & New Jersey, One World Trade Center, Suite 2121, New York, New York 10048.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Port Authority of New York & New Jersey under 14 CFR § 158.23.

FOR FURTHER INFORMATION CONTACT: Mr. Philip Brito, Manager, New York Airports District Office, 600 Old County Road, Suite 446, Garden City, New York 11530 (Telephone 516–227–3800). The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comments on the application to impose and use the revenue from a PFC at JFK, LGA, and EWR under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On July 21, 1997, the FAA determined that the applications to impose and use the revenue from a PFC submitted by the Port Authority of New York & New Jersey were substantially complete

within the requirements of 14 CFR part 158 (§ 158.25). The FAA will approve or disapprove the applications, in whole or in part, no later than November 16, 1997. However, the FAA will make no decision on the use application until the Port Authority, the Federal Highway Administration, and the New York State Department of Transportation finalize the Transportation Conformity process.

The following is a brief overview of the application.

Applications number: 97–04–C–00–JFK, LGA, EWR.

Level of the proposed PFC: $3.00.

Proposed charge effective date: September 1, 1997.

Proposed charge expiration date: December 1, 2009.

Total estimated PFC revenue: $1,248,000,000.

Brief description of proposed projects:

The Port Authority of NY & NJ request authority to use PFC revenue on two projects previously approved for collection:

1. Construct a Light Rail System (LRS) to serve the JFK Central Terminal Area (CTA).

2. Construct a 3.3 mile LRS connecting the NYCT Howard Beach Subway Station to the JFK CTA.

The Port Authority of NY & NJ also request the authority to impose and use PFC's for one new project:

—Construct a 3.1 mile long LRS connecting the LIRR Jamaica Station to the NYCT Howard Beach LRS

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: Air taxi, except commuter air carriers.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA regional Airports office located at: Fitzgerald Federal Building, John F. Kennedy International Airport, Jamaica, New York, 11430.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the office of the Port Authority of New York & New Jersey.

Issued in Jamaica, New York on July 21, 1997.

William DeGraaff,

Assistant Manager, Airports Division, Eastern Region.

[FR Doc. 97–19856 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 32760 (Sub–No. 23)]

Railroad Operation, Acquisition, Construction, Etc.: Union Pacific Corp, et al.

AGENCY: Surface Transportation Board.

ACTION: Notice that the Board has been requested to issue a finding that the terms and conditions of the proposed merger of St. Louis Southwestern Railway Company into SSW Merger Corp. are just and reasonable.

SUMMARY: St. Louis Southwestern Railway Company, approximately 99.96% of the common stock of which is owned by Southern Pacific Transportation Company, is to be merged into SSW Merger Corp., 100% of the common stock of which is owned by Southern Pacific Transportation Company. The merger envisions, among other things, a ''cashing out,'' at a price of $6,800 per share, of the four shareholders who own the approximately 0.04% of the common stock of St. Louis Southwestern Railway Company that is publicly held (61 out of 173,300 shares). The Board has been requested to issue a finding that the terms and conditions of the merger are just and reasonable.

DATES: Comments must be filed by August 28, 1997. Replies must be filed by September 12, 1997.

ADDRESSES: All pleadings should refer to STB Finance Docket No. 32760 (Sub-No. 23). Comments (an original and 10 copies) and replies (an original and 10 copies) should be sent to the Surface Transportation Board, Office of the Secretary, Case Control Unit, ATTN.: STB Finance Docket No. 32760 (Sub-No. 23), 1925 K Street, NW., Washington, DC 20423–0001. Comments should also be served (one copy each) on Arvid E. Roach II, Covington & Burling, 1201 Pennsylvania Avenue, NW., P.O. Box 7566, Washington, DC 20044–7566. Replies should also be served (one copy each) on the four shareholders who own the 61 publicly held shares of the common stock of St. Louis Southwestern Railway Company and on any other persons filing comments.

FOR FURTHER INFORMATION CONTACT: Julia M. Farr, (202) 565–1613. [TDD for the hearing impaired: (202) 565–1695.]

SUPPLEMENTARY INFORMATION: In Decision No. 44 in Finance Docket No. 32760, Union Pacific Corporation, Union Pacific Railroad Company, and Missouri Pacific Railroad Company—Control and Merger—Southern Pacific Rail Corporation, Southern Pacific Transportation Company, St. Louis Southwestern Railway Company, SPCSL Corp., and The Denver and Rio Grande Western Railroad Company (UP/SP), we approved the common control and merger of the rail carriers controlled by Union Pacific Corporation (Union Pacific Railroad Company and Missouri Pacific Railroad Company) and the rail carriers controlled by Southern Pacific Rail Corporation (Southern Pacific Transportation Company, St. Louis Southwestern Railway Company, SPCSL Corp., and The Denver and Rio Grande Western Railroad Company).[1]

The common control authorized in UP/SP, Decision No. 44, was consummated on September 11, 1996, with the merger of SPR with and into UP Holding Company, Inc., a direct wholly owned subsidiary of UPC.

In the application filed on November 30, 1995, applicants had noted, among other things, that, in effectuating UP/SP common control, they intended to merge SPT, SSW, SPCSL, and DRGW into UPRR, although they added that these companies might retain their separate existence for some time. See UP/SP, Decision No. 44, slip op. at 8. With respect to SSW, applicants specifically noted that, although SSW had a small number of minority equity holders and although the Federal Railroad Administration (FRA) held certain SSW redeemable preference shares, the application did not include a request for a Schwabacher determination[2] with respect to the compensation that might be paid to SSW security holders in connection with a merger of SSW into UPRR. Applicants added, however, that, if they later determined to carry out such a merger, they would request either a Schwabacher determination respecting the terms of the merger or a declaratory order that no such determination was

[1] In UP/SP, Decision No. 44: Union Pacific Corporation was referred to as UPC; Union Pacific Railroad Company was referred to as UPRR; Missouri Pacific Railroad Company was referred to as MPRR; UPRR and MPRR were referred to collectively as UP; Southern Pacific Rail Corporation was referred to as SPR; Southern Pacific Transportation Company was referred to as SPT; St. Louis Southwestern Railway Company was referred to as SSW; SPCSL Corp. was referred to as SPCSL; The Denver and Rio Grande Western Railroad Company was referred to as DRGW; SPT, SSW, SPCSL, and DRGW were referred to collectively as SP; UPC, UP, SPR, and SP were referred to collectively as ''applicants''; and the application that had been filed by applicants on November 30, 1995, was variously referred to as ''the application'' and ''the primary application.''

[2] The reference is to *Schwabacher* v. *United States*, 334 U.S. 192 (1948).

required. See UP/SP, Decision No. 44, slip op. at 8 n.6 (second paragraph).

By petition (designated UP/SP–306) filed July 17, 1997, the remaining applicants (UPC, UPRR, SPR, SPT, and SSW, hereinafter referred to simply as ''applicants'') indicate: that MPRR was merged into UPRR on January 1, 1997; that SPCSL and DRGW were merged into UPRR on June 30, 1997; that the corporate restructuring of the UP/SP system will be completed in February 1998 with the merger of SPT into UPRR; and that, prior to and in anticipation of the merger of SPT into UPRR, SSW will be merged into SSW Merger Corp. Applicants seek, in the UP/SP–306 petition, a determination that the terms of the proposed merger of SSW into SSW Merger Corp. (in particular, the $6,800-per-share price to be paid to the four shareholders who own the 61 shares of SSW's common stock that are publicly held) are just and reasonable.[3]/ Applicants seek this determination (1) because they believe the Board is required by Schwabacher to make such a determination to protect minority shareholders, and (2) in order to immunize the merger of SSW into SSW Merger Corp. from the otherwise applicable state law rights, particularly the otherwise applicable state law appraisal rights, of the four remaining public shareholders. 49 U.S.C. 11321(a).

Applicants urge expedited handling of their petition (in particular: that we publish notice of their petition in the **Federal Register**; that we allow interested persons 30 days to file comments; that we further allow applicants an additional 15 days to file a reply; and that we proceed promptly to a decision thereafter). Expedited handling is sought so that there will be, among other things, no unnecessary waste of resources associated with the need to maintain a formal distinction between SSW and the other rail carriers that have already been merged into UPRR. Applicants indicate that UP/SP will incur significant costs if it is unable to merge SSW into SSW Merger Corp. before September 30, 1997; unless that merger is completed before the end of the fiscal third quarter, applicants note, UP/SP will be required to go to the considerable time, expense, and difficulty of preparing financial statements that reflect the operations of SSW as a separate entity.

Applicants indicate that they are serving a copy of their UP/SP–306 petition ''on all active parties in this proceeding,'' UP/SP–306 at 14 (lines 2–3),[4] and that they will serve a copy ''on any known SSW shareholders,'' UP/SP–306 at 14 (lines 3–4).[5]

Our statutory mandate, 49 U.S.C. 11324(c), requires, among other things, that we determine, in appropriate cases, that the terms and conditions of certain transactions affecting stockholders are just and reasonable. See, e.g., Union Pacific Corp. et al.— Cont.—MO–KS–TX Co. et al., 4 I.C.C.2d 409, 515 (1988) (''In appraising this transaction affecting the rights of stockholders, it is incumbent upon us to see that the interests of minority stockholders are protected and that the overall proposal is just and reasonable to those stockholders. *Schwabacher* v. *United States,* 344 U.S.C. at 198, 201.''). Because the UP/SP–306 petition implicates our statutory mandate and involves a matter that requires expedited regulatory action, we will proceed upon the schedule urged by applicants.

Accordingly, we solicit comments from all interested persons respecting whether the terms and conditions of the proposed merger of SSW into SSW Merger Corp. are just and reasonable. Such comments must be submitted by August 28, 1997. Applicants may file replies to such comments by September 12, 1997.

Any interested person who has not received a copy of the UP/SP–306 petition may request a copy, in writing or by telephone, from Arvid E. Roach II, Covington & Burling, 1201 Pennsylvania Avenue, NW., P.O. Box 7566, Washington, DC 20044–7566 (telephone: 202–662–5388).

Not later than the fifth day after the date of publication of this decision, applicants should serve a copy of this decision upon the four public SSW shareholders and should certify to us: that service of this decision upon those four persons has been made; and that service of the UP/SP–306 petition upon such persons, to the extent such service was not made prior to the date of publication of this decision, has been made no later than the fifth day after the date of publication of this decision.

In addition to submitting an original and 10 copies of all documents filed with the Board, applicants and any commenters are requested to submit all pleadings and attachments as computer data contained on a 3.5-inch floppy diskette formatted for WordPerfect 7.0 (or formatted so that it can be converted by WordPerfect 7.0).

Decided: July 22, 1997.

By the Board, Chairman Morgan and Vice Chairman Owen.

Vernon A. Williams,

Secretary.

[FR Doc 97–19927 Filed 7–28–97; 8:45 am]

BILLING CODE 4915–00–P

[3] Applicants indicate that, prior to and independent of the merger, the shares of SSW preferred stock that are publicly held will be redeemed at par value pursuant to their terms. See UP/SP–306 at 1 n.2. Applicants further indicate that they have reached an agreement with FRA regarding the treatment of the FRA preference shares, which will remain in existence as obligations of the merged company. See UP/SP–306 at 3 n.4.

[4] This apparently has reference to the parties of record in the UP/SP oversight proceeding. See the UP/SP–306 certificate of service (on the unnumbered page following p. 16). See also Union Pacific Corporation, Union Pacific Railroad Company, and Missouri Pacific Railroad Company—Control and Merger—Southern Pacific Rail Corporation, Southern Pacific Transportation Company, St. Louis Southwestern Railway Company, SPCSL Corp., and The Denver and Rio Grande Western Railroad Company, STB Finance Docket No. 32760 (Sub-No. 21) (Decision No. 2, served June 19, 1997; Decision No. 3, served June 30, 1997; Decision No. 4, served July 16, 1997) (these decisions list the parties of record in the oversight proceeding).

[5] We assume that this refers to the four persons listed on the UP/SP–306 certificate of service (on the unnumbered page following p. 16).

Corrections

Federal Register

Vol. 62, No. 145

Tuesday, July 29, 1997

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPD-889-NC]

RIN 0938-AH88

Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning on or After July 1, 1997

Correction

In notice document 97–17235 beginning on page 35608 in the issue of Tuesday, July 1, 1997, make the following corrections:

1. On page 35614, in the first column:

a. In the second example (2.), in the equation line above Step 3, equation ''11.58995÷10=158995'' should read ''11.58995÷10=1.158995''.

b. In the second example (2.), Step 6, letter a, the equation line, ''$79.01×1.01199=$79.89'' should read ''$79.01×1.011099=$79.89''.

2. On page 35615, in the first table, in the last entry line ''Aggregate cost limit'' in the fifth column over ''Aggregate limit'', ''918,5501'' should read ''918,550''

3. On the same page, in the second table, in the column entitled ''Limit'', the first entry ''101.20'' should read ''101.29''.

4. On page 35619, the first and second entries on that page, ''DuPage, IL, Grundy, IL'' should read first entry ''DuPage, IL'', second entry ''Grundy, IL''.

5. On page 35624, in the first column, fourth entry from the bottom, ''4480*'' should read ''4480''.

6. On the same page, in the same entry line, in the second column ''Urban area (Constituent counties or county equivalents)'' ''Los Angeles-Long Beach CA'' should read ''*Los Angeles-Long Beach, CA''.

7. On page 35628, in the ''Wage index'' column, the third entry, ''1.01116'' should read ''1.0116''.

8. On page 35630, in entry line beginning with ''7560'', in the second column ''Urban area (Constituent counties or county equivalents)'', ''Scranton-Wilkes-Barre-Hazelton, PA'' should read ''Scranton--Wilkes- Barre--Hazelton, PA''.

BILLING CODE 1505-01-D

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-372]

The Economic Implications of Liberalizing APEC Tariff and Nontariff Barriers to Trade

Correction

In document 97–19400 beginning on page 39539 in the issue of Wednesday July 23, 1997, make the following correction:

On page 39540, in the second column, at the bottom of the page, ''Issued: July 14, 1979.''' should read ''Issued: July 14, 1997.''

BILLING CODE 1505-01-D

Federal Register

Tuesday
July 29, 1997

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 10, et al.

National Environmental Policy Act; Revision of Policies and Procedures; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 20, 25, 71, 101, 170, 171, 312, 314, 511, 514, 570, 571, 601, 812, and 814

[Docket No. 96N–0057]

National Environmental Policy Act; Revision of Policies and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing compliance with the National Environmental Policy Act of 1969 (NEPA) as implemented by the regulations of the Council on Environmental Quality (CEQ). The primary purpose of this final rule is to increase the efficiency of FDA's implementation of NEPA and to reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an environmental impact statement (EIS) nor an environmental assessment (EA) is required. FDA is also amending its regulations to make its NEPA procedures more concise and understandable to the public and to reflect current FDA policy with respect to environmental considerations. The amendments to FDA's regulations governing compliance with NEPA reflect FDA's continuing review of its policies and procedures to determine whether revisions are necessary to ensure full compliance with the purpose and provisions of NEPA and implement the President's reinventing Government initiatives announced in ''Reinventing Drug and Medical Device Regulations,'' April 1995, and ''Reinventing Food Regulations,'' January 1996.

DATES: The regulations are effective on August 28, 1997. For applications or petitions pending before the agency on August 28, 1997, for which the agency has not signed a finding of no significant impact (FONSI) on or before August 28, 1997, the applicant or petitioner may submit an amendment to the application or petition under 21 CFR 10.30(g), 71.6(b), 171.6, 314.60, 514.6, 571.6, 601.2 or 814.37 claiming a categorical exclusion in accordance with § 25.15(d) of this final rule. The applicant or petitioner should state in the amendment that the applicant or petitioner waives the claim for categorical exclusion if a FONSI has been signed on or before August 28, 1997.

FURTHER INFORMATION CONTACT:

For information regarding human drugs:
Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5629

For information regarding biologics:
Daniel C. Kearns, Center for Biologics Evaluation and Research (HFM–208), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3031

For information regarding veterinary medicines:
Charles E. Eirkson, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1683

For information regarding foods:
Buzz L. Hoffmann, Center for Food Safety and Applied Nutrition (HFS–246), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3005

For information regarding medical devices and radiological health:
Mervin O. Parker, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 3, 1996 (61 FR 14922) (republished May 1, 1996 (61 FR 19476)), FDA proposed to amend its regulations in part 25 (21 CFR part 25) governing compliance with NEPA as implemented by the regulations of CEQ. FDA provided 90 days for public comment on the proposed rule. In addition, in the **Federal Register** of October 22, 1996 (61 FR 54746), FDA announced the placement in the administrative record of additional information and underlying data concerning the proposed rule, and granted a 30-day comment period permitting interested parties to submit comments relating to those categorical exclusions for which additional information was provided. The agency has revised portions of the final regulations in response to comments received on the proposal.

This final rule amending FDA's NEPA procedures increases the efficiency of the agency's implementation of NEPA by substantially reducing the number of EA's required to be submitted by industry and reviewed by FDA and by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant impact on the human environment. This final rule also makes the regulations more concise and useful to the public and regulated industry.

II. Comments on the Proposed Rule

FDA received 17 letters, including letters from manufacturers, trade associations, environmental groups, academics, environmental consultants, and the U.S. Environmental Protection Agency (EPA), commenting on the proposed rule. In general, the comments supported FDA's proposed revisions to more efficiently implement NEPA. One manufacturer of human and veterinary pharmaceuticals projected that the final rule would reduce by 75 percent the number of its products that will require EA's, and a pharmaceutical industry trade association estimated that the rule will reduce by 90 percent the amount of environmental information submitted to the agency. FDA's analysis of the impacts of this final rule is included in section III of this document, ''Analysis of Impacts.''

A. Subpart A—General Provisions

1. One comment stressed the need to have more interaction and greater alignment among the agencies involved in implementing NEPA in order to develop more consistent policies.

CEQ regulations direct agencies with similar programs to consult with each other and with CEQ to coordinate their procedures (40 CFR 1507.3). However, differences in Federal agencies' policies and procedures to implement NEPA are inevitable because each agency has its own distinct statutory mandates. Each agency needs to evaluate and prioritize different environmental risks based on the nature of the agency's actions. CEQ reviews the procedures of all agencies to ensure their conformity with NEPA and CEQ regulations. FDA consults and coordinates with other Federal agencies regarding the protection of the environment to the fullest extent possible.

2. Proposed § 25.5(b)(4) states that increased use of a drug or biologic product may occur if the drug may be administered at higher dosage levels, for longer duration or for different indications than were previously in effect, or if the drug is a new molecular entity. This section further defines new molecular entity as, ''a drug for which the active moiety * * * has not been previously approved or marketed in the

United States for use in a drug product, either as a single ingredient or as part of a combination product or as part of a mixture of stereoisomers.'' FDA has decided not to include the definition of new molecular entity in § 25.5(b)(4). The term is currently defined in guidance documents issued by the Center for Drug Evaluation and Research (CDER). The agency does not find it necessary to include the definition in its regulations. Parties interested in the definition of new molecular entity should consult the information available from CDER.

3. Proposed § 25.10(c) describes when the environmental planning process begins under NEPA: ''For actions initiated by applicants or petitioners, NEPA planning begins when FDA receives a submission from an applicant or petitioner seeking action by FDA.'' Proposed § 25.10(c) differs from current § 25.10(a), which states that:

> For actions initiated by applicants or petitioners, the process begins when FDA receives from an applicant or petitioner an environmental assessment (EA) or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions.

One comment indicated that current § 25.10(a) is consistent with NEPA and CEQ regulations because it provides for consultation between the agency and applicants or petitioners prior to Federal action. However, the comment contended that proposed § 25.10(c), as it amends current § 25.10(a), is inconsistent with NEPA and CEQ regulations. The comment specifically cites an inconsistency between proposed § 25.10(c) and 40 CFR 1501.2(d), which states that in ''cases where actions are planned by private applicants or other non-Federal entities before Federal involvement,'' agencies shall provide policies or designated staff members ''to advise potential applicants of studies or other information foreseeably required for later Federal action,'' and shall begin the NEPA process ''at the earliest time possible.''

FDA agrees with the comment. As explained in the preamble to the proposal (61 FR 14922 at 14923, 61 FR 19476 at 19477), FDA intended to eliminate unnecessary language by combining § 25.5 (Policies) and § 25.10 (NEPA planning) into proposed § 25.10 (Policies and NEPA planning). FDA did not intend to change the timing of the initiation of the agency's environmental planning process or to preclude early consultation with FDA prior to Federal action when it proposed the language in § 25.10(c). Thus, because the proposed section does not clearly express the agency's policy, the agency will incorporate the current § 25.10(a) language, and § 25.10(c) will provide, in relevant part:

> For actions initiated by applicants or petitioners, NEPA planning begins when FDA receives from an applicant or petitioner an environmental assessment (EA) or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions.

4. One comment stated that under CEQ regulations (40 CFR 1501.2(d)), FDA is required to ensure that potential applicants or petitioners prepare an EA prior to the harvest of natural resources, such as the Pacific yew tree, regardless of whether the drug sponsor has filed an application or petition with the agency. The comment requested that the proposed regulations be revised to specifically address the issue of ''stockpiling'' harvested material prior to submitting an application or petition.

The requirements and procedures of NEPA are triggered by a major Federal action. Until FDA reviews an application or petition, initiates an action, or is consulted regarding potential agency action, no action exists to set the NEPA process in motion, and there is no regulatory requirement for applicants or petitioners to inform FDA of their use of natural resources prior to the submission of an application or petition to FDA. Therefore, FDA cannot ensure that applicants or petitioners prepare an EA prior to the harvest of natural resources. In accordance with 40 CFR 1501.2(d), the agency makes staff available to advise potential applicants or petitioners of studies or other information foreseeably required for later Federal action and commences its NEPA process at the earliest possible time (see § 25.10(c) of this final rule). FDA will request information about stockpiling and harvesting once the NEPA process is triggered by a proposed action.

With regard to the comment's specific concerns about the Pacific yew, the agency published a notice in the **Federal Register** of November 18, 1996 (61 FR 58694), clarifying the environmental information that must be submitted to the agency with a new drug application (NDA), abbreviated new drug application (ANDA), or investigational new drug application (IND) involving paclitaxel derived from or otherwise involving the Pacific yew.

5. One comment requested that proposed § 25.10, which states FDA's overall policy in implementing the NEPA requirements, be modified to indicate that applicants should be involved in the development of agency policies, procedures, and guidance documents that are designed to interpret, clarify, or elaborate on the requirements placed on applicants to satisfy FDA's statutory obligations under NEPA.

In a notice in the **Federal Register** of February 27, 1997 (62 FR 8961), FDA announced its ''Good Guidance Practices'' (GGP's), which represents the agency's policy regarding the development and use of guidance documents (hereinafter referred to as the GGP's notice). The GGP's address public participation in the guidance document development process generally. FDA does not believe that it is necessary or appropriate to address public participation in the NEPA guidance document development process specifically. Interested individuals are encouraged to review the **Federal Register** notice and related comments (Docket No. 95P–0110).

6. One comment requested that § 25.10 be revised to provide that a single center official be responsible for addressing and resolving questions raised by reviewers and for mediating conflicts arising between reviewers and sponsors regarding interpretations of the regulatory requirements. The comment also requested that a provision be included that establishes an appeal from the center's responsible official to the Center Director, in the event that the center official is unable to resolve questions raised by reviewers.

FDA does not believe it is necessary to revise proposed § 25.10 as suggested by the comment. Individuals in each center with specialized training and expertise oversee the NEPA review process, resolve questions raised by reviewers, and mediate conflicts between reviewers and sponsors. Actions by reviewers or other center officials may be appealed through the appeals mechanisms already in place in each center to the Center Director and, ultimately, to the Commissioner of Food and Drugs (the Commissioner). Individuals who are interested in obtaining copies of the appeals procedures established in each center may contact the relevant center for such information.

B. Subpart B—Agency Actions Requiring Environmental Consideration

7. Proposed § 25.15(a) states that the failure of an applicant or petitioner to submit an ''adequate EA'' for a requested action that is not categorically excluded is sufficient grounds for FDA to refuse to file or approve the application or petition. One comment noted that while FDA requires an ''adequate'' EA, the definition of that

term found in current § 25.22(b) is not included in the proposed regulations. The comment requested that the agency retain the definition of adequate EA in its regulations.

The agency agrees that clarification of when an EA is adequate for filing or approval is appropriate. Consequently, proposed § 25.15(a) has been revised to include the clarifying statements currently found in § 25.22(b):

> An EA adequate for filing is one that addresses the relevant environmental issues. An EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment.

8. Proposed § 25.15(a) and (d) requires that applicants and petitioners who claim that a categorical exclusion applies to a proposed action certify that the action qualifies for a categorical exclusion, citing the particular exclusion that is claimed, and certify that to their knowledge no extraordinary circumstances exist. One comment specifically welcomed and believed important to the success of FDA's proposals the certification of compliance with the categorical exclusion criteria required in § 25.15(a) and (d). Another comment requested clarification of the certification requirement in § 25.15(a) and (d), questioning whether the categorical exclusion document needs to contain a separate certification indicating the truthfulness and accuracy of the information provided in the certification, or whether the categorical exclusion document alone is sufficient.

Applications and petitions that are filed with the agency are signed by a responsible agent or official of the sponsor, who attests to the truth and accuracy of the information within the application or petition. A separate, signed categorical exclusion document is not needed. Under § 25.15(a) and (d), FDA requires that an applicant or petitioner requesting a categorical exclusion identify the categorical exclusion being claimed, state that the action complies with the categorical exclusion criteria, and state that to the applicant's knowledge no extraordinary circumstances exist. For clarification, § 25.15(a) and (d) have been modified to indicate that a statement, not a certification, is needed.

9. One comment contended that proposed § 25.15(a) and (d) is inconsistent with CEQ regulations in that the CEQ regulations require that the agency use specific criteria to judge whether an action fits within a categorical exclusion (40 CFR 1507.3(b)(2)(ii)) and independently evaluate the information submitted and be responsible for the accuracy of the information (40 CFR 1506.5). The comment also asserted that proposed § 25.15(a) and (d) departs from existing FDA regulations, which require that applicants claiming a categorical exclusion provide supporting information that the action meets the criteria for the applicable exclusion.

Under current § 25.23(c), a person who claims a categorical exclusion provides information when appropriate that establishes to the agency's satisfaction that the action meets the criteria for the applicable exclusion (emphasis added). Proposed § 25.15(a) and (d) does not reflect a departure from current FDA regulations. In revising its NEPA procedures, FDA has formulated its categorical exclusions to include specific criteria, as required by CEQ's regulations (40 CFR 1507.3(b)(2)(ii)) that in most instances can either be facially determined or confirmed by review of other information submitted as part of the request for action. This approach is consistent with CEQ's view that in most cases additional information should not be required. In the limited instances when it may be necessary, FDA will request additional information as needed to establish to the agency's satisfaction that the criteria for a categorical exclusion have been met.

10. One comment objected to the absence of information in the proposal concerning the actions FDA may take in response to a petitioner or applicant filing a false certification with the agency.

It is a violation of the criminal code (18 U.S.C. 1001) for anyone, in any matter within the jurisdiction of any department or agency of the United States, to knowingly and willfully make any false, fictitious, or fraudulent statement or representation to such department or agency. Enforcement decisions are generally a matter of an agency's discretion. FDA will exercise its enforcement discretion consistent with its statutory responsibilities under all applicable statutes, including NEPA.

11. One comment recommended that the basic physical/chemical characterization of a potential product be included in all EA documents including claims for categorical exclusion.

In the event FDA determines that basic physical/chemical characterization information is relevant to its environmental consideration of a specific proposed action, FDA will request that such information be provided in an EA. FDA intends to issue guidance documents that will provide applicants with information about the nature and scope of information that should be included in an EA. A claim for categorical exclusion shall comply with § 25.15(a) and (d) and, as discussed in the response to comment 9, should not normally include additional information.

12. Proposed § 25.20 lists broad categories of agency actions that require the preparation of an EA, unless the action qualifies for exclusion. One comment noted that although FDA stated in the preamble to the proposal that the types of actions requiring an EA remain essentially the same as in current § 25.22, the proposal did not include the ''catch-all action'' in current § 25.22(a)(19): ''Action other than one listed in this subsection, unless subject to exclusion under §§ 25.23 and 25.24, that may significantly affect the quality of the human environment.'' The comment recommended that a clause be retained in new § 25.20 providing that an ''EA must be prepared for an action other than one listed in (§ 25.20) that may significantly affect the quality of the human environment.''

The list of actions requiring preparation of an EA was not intended to be all-inclusive. The list includes broad classes of actions that require preparation of at least an EA, unless categorically excluded in subpart C of part 25. Under NEPA and CEQ's implementing regulations, FDA is required to consider the environmental impact of each of its proposals for major Federal action that is not categorically excluded. Therefore, it is not necessary for FDA to include the described catch-all clause in the final rule.

13. Another comment noted that proposed § 25.20(i) requires an EA for actions on requests for exemptions for investigational use of food additives, unless categorically excluded under proposed § 25.32(b), and questioned whether the agency expects a claim for exclusion to be submitted for actions involving investigational food additives. The comment asked FDA to clarify its intent.

The intent of the provision in proposed § 25.20(i) is to identify actions involving food additives that ordinarily require an EA, unless the actions are in a specific class that qualifies for a categorical exclusion. Similar to the agency's experience with actions on investigational human and animal drugs, FDA expects that if action were taken on an investigational food additive, such action would qualify for the exclusion under § 25.32(b) of the final rule.

14. Proposed § 25.21 addresses ''extraordinary circumstances'' under which categories of actions that would

ordinarily be categorically excluded would require preparation of an EA. One comment contended that this exception to categorical exclusions will result in the potential for ''regulatory creep,'' that is, the potential for FDA to implement the exception in a manner that results in an expansion of the degree of FDA review, a lengthening of time for review, and an increased cost of review. The comment expressed particular concern about the opportunity for regulatory creep in relation to applying the exception to categorical exclusions for actions on new animal drug applications (NADA's). The comment suggested that a primary safeguard against misuse of the extraordinary circumstances exception is to ensure that decisions on exceptions are reserved and delegated in part 5 (21 CFR part 5) to a truly responsible official; in the case of actions on animal drugs, to the Director of the Center for Veterinary Medicine.

As the comment recognizes, under CEQ regulations at 40 CFR 1508.4, FDA is required to provide for extraordinary circumstances in which a normally excluded action may have a significant effect on the environment. Under proposed § 25.21 (current § 25.23(b)), FDA requires an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment. CEQ regulations, in 40 CFR 1508.27, define ''significantly'' to require consideration of both the context and intensity of an agency action. Proposed § 25.21 cites § 1508.27 to emphasize that, in implementing its regulations, FDA will rely on the principles established by CEQ for determining whether an extraordinary circumstance exists such that an action, ordinarily excluded, may significantly affect the environment. By definition, a categorical exclusion means a category of actions that has been found not to have a significant effect on the human environment, therefore application of the extraordinary circumstances provision should be limited. Since 1985, in implementing its NEPA procedures, FDA has invoked the extraordinary circumstance exception to categorical exclusions in limited instances and in a manner consistent with CEQ regulations. Section 25.21 lists two examples of extraordinary circumstances where FDA may apply the exception.

FDA declines to modify part 5 to reflect that the authority to determine the existence of extraordinary circumstances related to animal drugs is reserved to the Director of the Center of Veterinary Medicine. The agency's decision is described in the response to comment 60 below, which discusses the revision of part 5 with respect to all FDA Center Directors.

15. One comment asserted that the extraordinary circumstances provision will not result in the preparation of EA's for applications involving paclitaxel that otherwise meet the criteria for categorical exclusion. The comment stated that the Pacific yew is not classified as an endangered or threatened species under the Endangered Species Act (ESA), nor is the species currently listed in any of the appendices to the Convention on International Trade in Endangered Species of Fauna and Flora (CITES) and expressed concern that agency actions regarding products containing paclitaxel would escape environmental consideration because they do not fall within FDA's examples of extraordinary circumstances. The comment also questioned the standard that the agency has proposed to use in determining whether an action involving wild flora and fauna falls within FDA's second example of extraordinary circumstances, citing FDA's statement in the preamble that the agency:

> (I)ntends to closely examine proposed actions that involve FDA-regulated articles obtained from wild flora and fauna and will use the extraordinary circumstances provision to require at least an EA in any instance in which it appears from an examination of the proposed action that the action may cause a species to become endangered or threatened.

Finally, the comment asserted that unlike the ESA, CITES does not speak in terms of endangered or threatened species.

The examples provided by the agency in proposed § 25.21 are illustrative of the types of action that would require an EA despite the fact that the action otherwise qualifies for a categorical exclusion. The two examples are not intended to be an exhaustive list of those actions.

FDA's extraordinary circumstances provision requires that an EA be prepared if a normally excluded action may significantly affect the quality of the human environment. FDA has specifically determined that actions relating to applications involving paclitaxel derived from or otherwise involving the Pacific yew tree fall within the CEQ definition of ''significantly'' (40 CFR 1508.27) and has documented, in the agreement filed in the U.S. District Court for the District of Columbia in *Oregon Natural Resources Council Action* v. *Shalala*, No. 96–1449 PLF (D.C.D.C. Oct. 4, 1996), its intent to require EA's for all actions on applications, except some actions on IND's, involving paclitaxel derived from or otherwise involving the Pacific yew tree. FDA also published a notice in the **Federal Register** clarifying the environmental information that must be submitted to the agency in marketing applications for drug products containing paclitaxel (61 FR 58694).

FDA is clarifying that it will require an EA for an action, including one involving wild flora and fauna, that is ordinarily excluded if the action may have a significant effect on the environment. Where a species of wild flora or fauna may become endangered or threatened, the action may have a significant effect.

The comment is inaccurate in stating that CITES does not speak in terms of endangered or threatened species. The regulations implementing CITES (50 CFR 23.2) note that the appendices include endangered and threatened species and a ''Facts'' sheet published by the Fish and Wildlife Service explains that Appendix I includes species presently threatened with extinction.

16. One comment expressed concern about the environmental effects of synthetic estrogens in the aquatic environment, specifically those synthetic estrogens in oral contraceptives and estrogenic replacement therapy prescribed for post-menopausal women. The comment requested that until research is available to determine a more accurate critical concentration, FDA consider the use of synthetic estrogens in human drugs to be an extraordinary circumstance so that actions involving estrogen use would require an EA. The authors of the comment state that they have observed significant alterations of gender ratios when developing larval medaka (a fish) were exposed to 0.1 part per billion (ppb) of 17β-estradiol (naturally occurring) for 4 weeks. Additionally, they cite from a published article that male rainbow trout exposed to 0.002 ppb ethinyl estradiol (used in oral contraceptives) for 3 weeks showed significantly elevated vitellogenin levels and decreased testes weight and compromised spermatogenesis. Concern was also expressed about the potential for higher concentrations of these compounds in certain local areas.

FDA will require an EA for any specific action that ordinarily would be excluded if available evidence establishes that, at the expected level of exposure, a potential exists for a significant effect on the environment.

The agency has considered the request that the use of synthetic estrogens in human drugs be considered an extraordinary circumstance, but has concluded that the available evidence does not support that, at the expected level of exposure, a potential exists for significant effect on the environment. FDA has considered many factors in arriving at this conclusion including normal prescribing patterns for the drugs, medical uses, pharmacological properties, waste water treatment practices and expected introduction and environmental concentrations of the substances. FDA provided its analysis to the EPA for review and EPA agreed with FDA's position on this issue. Therefore, FDA will not generally apply the extraordinary circumstances exception to actions involving synthetic estrogens used in oral contraceptives and hormone replacement therapy that otherwise meet the criteria for categorical exclusion. A report explaining the basis of the agency's decision has been placed in Docket No. 96N–0057. FDA will continue to investigate this issue in general and assess each action on an individual basis to determine whether an extraordinary circumstance exists.

17. Proposed § 25.22 provides for the preparation of an EIS when the responsible agency official finds, as a result of evaluating relevant data and information, that a proposed action may significantly affect the quality of the human environment. One comment recommended that FDA establish specific criteria to determine the need to prepare an EIS. The comment suggested that the agency base the criteria on the number of potentially affected parties or on the formula used by the European Union (EU) to trigger the EU equivalent of an EIS. The EU criteria are based on annual tonnage.

An EIS is prepared when evaluation of data or information in an EA or otherwise available to the agency leads to a finding that a proposed action may significantly affect the quality of the human environment. FDA does not believe it is necessary to further identify criteria for preparing an EIS. CEQ regulations (40 CFR 1508.27) define ''significantly'' and provide guidance to FDA in its determination of whether an action significantly affects the environment. Furthermore, it is difficult to develop criteria that are more specific and that may be applied with great frequency. Criteria relating to the amount of material produced are not appropriate criteria for determining when an EIS must be prepared. For example, an EIS may not be necessary for FDA-regulated articles produced in large quantities if environmental depletion mechanisms are identified and/or the material is relatively nontoxic to environmental organisms at expected environmental concentrations.

18. In the preamble to the proposal, FDA stated that it is proposing to remove current § 25.25 (Retroactive environmental consideration) because any request by FDA to an applicant to submit additional information to an existing FDA approval will be made under authority granted to FDA by the Federal Food, Drug, and Cosmetic Act (the act) or the Public Health Service Act (the PHS Act). One comment contended that this proposed action is inconsistent with both CEQ regulations and case law governing implementation of NEPA. The comment stated that FDA was suggesting it could not comply with 40 CFR 1502.9(c)(1)(ii) because its authority to require additional environmental information from applicants only stems from the act or the PHS Act. The comment stated that the Federal court, in *Environmental Defense Fund* v. *Mathews,* 410 F.Supp. 336, 338 (D.C.D.C. 1976), rejected similar claims when FDA issued its NEPA regulations in the 1970's.

Because the comment misunderstands the agency's stated reasons for proposing to remove current § 25.25, FDA is clarifying them here. Current § 25.25 applies to agency consideration of the need to prepare an EIS after the agency has already taken an action, e.g., promulgation of a regulation or action relating to an approval. NEPA and CEQ regulations both require an agency to consider the environmental impact of its actions before decisions are made and before actions are taken. Thus, the agency must prepare an EIS for an action it has found may significantly affect the environment before it takes the action. NEPA does not apply retroactively; instead, however, if an ongoing project undergoes changes which themselves amount to ''major Federal actions,'' the agency must then prepare an EIS (*Upper Snake River Chapter of Trout Unlimited* v. *Hodel,* 921 F.2d 232, 234 (9th Cir. 1990)). FDA is removing § 25.25, which concerned retroactive environmental consideration.

The comment cites *Environmental Defense Fund* v. *Mathews,* 410 F.Supp. 336, 338 (D.C.D.C. 1976), which relates to FDA's 1973 regulations implementing its obligations under NEPA. The case held that, in addition to its other statutory mandates, FDA has a nondiscretionary responsibility under NEPA to take environmental considerations into account in its process of decisionmaking. For the reasons stated above, elimination of current § 25.25 does not affect this responsibility and is not inconsistent with CEQ regulations or case law.

The agency specifically acknowledges its responsibility to prepare supplements in accord with § 1502.9 in the new regulations (see § 25.42(c)). FDA's discussion in the preamble to the proposed rule was intended to point out that CEQ regulations only discuss when a supplement to a draft or final EIS is needed. CEQ regulations do not specifically address or grant any authority to an agency to request additional information under other circumstances. FDA also wanted to make it clear that once FDA has taken an action, the agency has authority under the act and the PHS Act to request that an applicant submit additional information to an existing approval.

C. Subpart C—Categorical Exclusions

19. One comment found no major issues or problems with the policy and procedure revisions, but expressed concern whether FDA had made adequate analyses to substantiate the proposed categorical exclusions. Another comment stated that the commenter was unable to evaluate the proposed categorical exclusions, specifically the exclusion provided in § 25.31(b), because FDA had not made the information upon which it based its conclusions available to the public.

To provide additional substantiation for its proposed categorical exclusions, FDA supplemented the administrative record for the proposed regulations with additional information. On October 22, 1996, the agency published a notice in the **Federal Register** (61 FR 54746) announcing the availability of specific information, including underlying data, that along with the information in the preamble to the proposed rule supports the categorical exclusions. FDA also reopened the comment period for 30 days for the sole purpose of inviting public comment on those categorical exclusions for which information had been added to the administrative record. The agency received four comments during this extended comment period, three of which addressed categorical exclusions for drug and biologic products. FDA, therefore, believes that it has provided adequate explanation of the categorical exclusions and has provided adequate opportunity for comment on the categorical exclusions by interested parties.

20. Proposed § 25.30(j) revised the categorical exclusion for issuance of certain types of regulations, including current good manufacturing practice

(CGMP) regulations, to categorically exclude regulations based on the hazard analysis critical control points (HACCP) principles. One comment agreed with this change but recommended that HACCP programs incorporate mandatory self audits and independent audits into their requirements.

This recommendation is outside the scope of this rulemaking.

1. Human Drugs and Biologics

21. Proposed § 25.31(a) would categorically exclude FDA action on an NDA, abbreviated application, or a supplement to such applications, or action on an over-the-counter (OTC) monograph, if the action does not increase the use of the active moiety of the drug. FDA intended to include in this categorical exclusion applications for marketing approval of a biologic product. As discussed in the preamble to the proposed rule with regard to NDA's, abbreviated applications, supplements, and OTC monographs, if an action, including action on a marketing application for a biologic product, does not increase the use of the product, there is no change in the level of substance in the environment and, consequently, no increase in any environmental effects associated with the use and disposal from use of the product. Therefore, proposed § 25.31(a) has been modified as follows:

> Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

22. Proposed § 25.31(b) would categorically exclude FDA action on a marketing application for a human drug, or supplement to such application, or action on an OTC monograph, if the action increases the use of the active moiety but the concentration of the substance in the environment will be below 1 ppb. Several comments generally supported the 1 ppb criterion, but sought minor revisions to or clarifications of the criterion.

One comment suggested that the 1 ppb criterion be changed to 0.1 ppb using the predicted environmental concentration (PEC). PEC is defined as the introduction concentration, corrected based on metabolism/excretion data, on wastewater treatment facility fate information, and on the use of an appropriate stream dilution factor of 10. Two comments suggested that proposed § 25.31(b) be clarified to indicate that the relevant concentration is at the point of entry into the aquatic environment. One of these comments agreed that substances entering the environment at less than or equal to 1 ppb will have an insignificant environmental impact, but suggested that the standard be an expected introduction concentration because this would give more consideration to potential exposure to primary human receptors which may come in contact with the substance before it degrades or enters a wastewater treatment facility. Another comment suggested that because 1 ppb computes to a production rate of 40,700 kilograms (kg) per year using the calculation method provided in FDA guidance, FDA should add an exclusion for actions relating to human drugs for which the production rate of the active moiety is less than 40,700 kg per year.

FDA agrees to clarify that the 1 ppb requirement is relevant at the point of entry into the aquatic environment, that is, the environmental introduction concentration (EIC). Under current part 25, FDA requires EA's to initially provide an estimate of the quantity and concentration of the substance that is expected to enter the environment. The calculation method suggested by CDER is explained in its ''Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements'' (FDA, November 1995). If environmental fate and effects information for a substance is required in an EA, spatial and temporal concentration and depletion mechanisms will, as appropriate, be used to adjust the EIC to estimate the expected environmental concentration (EEC)/exposure concentration of the product. PEC, as defined by the comment, is the same as the EEC/exposure concentration. The comment's suggested use of a criterion of 0.1 ppb, calculated using a dilution factor of 10, is equivalent to the agency's proposed criterion of 1 ppb calculated without using a dilution factor, in that the same amount of the substance entering the environment would qualify for categorical exclusion under each proposal. It may be appropriate for FDA to consider a dilution factor when estimating a substance's EEC/exposure concentration, based on information provided in an EA, to evaluate the fate and effects of the substance. For the purposes of a categorical exclusion criterion, however, a conservative estimate of the concentration, EIC, will be used.

As explained in the preamble to the proposed rule (61 FR 14922 at 14925, 61 FR 19476 at 19479), based on their method of entry into the environment from use and their physical and chemical characteristics (e.g., water solubility), human drugs would be expected predominantly to enter the aquatic environment. The data submitted in EA's reviewed by CDER have routinely supported this hypothesis. The data also have routinely shown that in those cases in which an applicant has provided toxicity results for terrestrial organisms in addition to acute toxicity results for aquatic organisms, the drugs are toxic to aquatic organisms at lower levels than they are to terrestrial organisms, suggesting that the use of aquatic organisms is a conservative approach. Proposed § 25.31(b) has been revised to clarify that the relevant concentration is at the point of entry into the aquatic environment.

CEQ regulations require that localized (i.e., site-specific) effects of a substance on the environment be considered, where appropriate (40 CFR 1508.27(a)). Typically, the use of a drug product is spread throughout the United States. However, in the rare instance in which the use of a drug will be localized in one geographic area, a categorical exclusion based on the concentration of a substance at the point of entry into the aquatic environment, such as 1 ppb, provides for an evaluation of the local environmental effect of that drug. The suggestion to add a categorical exclusion based on a set quantity of the drug product, such as 40,700 kg, ignores the possibility of localized use that the agency is required to consider. Therefore, FDA is not adding a categorical exclusion based on production rates.

Concerning potential exposure to primary human receptors, as discussed in *Calorie Control Council, Inc.* v. *U.S. Department of Health, Education, and Welfare,* No. 77–0776 (D.C.D.C. 1977), the primary concern of NEPA is the impact of agency actions on physical environmental resources, not the public health consequences of a proposed action. Furthermore, NEPA authority is intended to supplement other statutory responsibilities of a Federal agency. FDA already addresses primary receptor issues as public health issues under the act rather than through NEPA evaluation.

As a result of this discussion, proposed § 25.31(b) has been revised to state:

> Action on a NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph, if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.

CDER's document, ''Guidance for Industry for the Submission of an

Environmental Assessment in Human Drug Applications and Supplements,'' provides a method for calculating the estimated concentration of the substance at the point of entry into the aquatic environment. Other calculation methods may be appropriate. However, such alternative calculations will be reviewed by the agency on a case-by-case basis to determine whether they are appropriate for determining whether the categorical exclusion applies.

23. One comment reiterated a comment made during the initial comment period that the agency needs to broaden ''extraordinary circumstances,'' especially as the provision relates to paclitaxel, and further noted ''troubling defects'' in the Toxicity Report the agency provided in the administrative record to support the 1 ppb categorical exclusion criterion in § 25.31(b). The defects cited in the comment include: (1) The report is grounded in an evaluation of ecotoxicity in a few select laboratory species, not in wild organisms that may already be stressed by other pollutants; (2) the report appears to be based on EA's submitted by applicants to the agency, and no information is given about how the toxicity figures were obtained and whether certain assumptions were made in the studies; (3) the report does not consider cumulative impacts associated with disposal of the products in the environment, including the potential for bioaccumulation of pollutants over time; and (4) the report provides no scientific explanation, other than citing one article, for dividing the median effective concentration (EC50) or median lethal concentration (LC50) values by 1,000 to arrive at a predicted no observed effect concentration (NOEC). The comment also stated that the Toxicity Report is based on toxicity tests that may be considered antiquated in light of recent efforts by the Organization for Economic Cooperation and Development (OECD) and EPA to revise such evaluations. The comment did not suggest any changes to the proposed regulations.

FDA's extraordinary circumstances provision requires that at least an EA be prepared if a normally excluded action may significantly affect the quality of the human environment. The agency has specifically determined that most actions relating to paclitaxel derived from or otherwise involving the Pacific yew require the preparation of EA's, irrespective of the expected concentration of paclitaxel at its point of entry into the aquatic environment. (See the response to comment 15, above.)

With respect to the alleged defects of the Toxicity Report, environmental risk assessment initially involves determining the toxic effect of a compound on a few select laboratory species. The test organisms used by the applicants to generate the data in the Toxicity Report are typically the same as those suggested by EPA (see 40 CFR 797) and OECD for this initial screening. CDER evaluates the potential for significant environmental effects by relating the concentrations determined to have toxic effects on these test organisms to the level of the substance expected in the environment. Field studies (i.e., evaluation in actual environmental settings) are generally conducted only when initial evaluation and subsequent intermediate evaluations indicate that the potential for significant environmental harm may exist.

FDA based the proposed 1 ppb categorical exclusion on toxicity data submitted to the agency in EA's. The agency's analysis of the toxicity data is explained in the Toxicity Report. Under 40 CFR 1506.5, the agency asks applicants to prepare an EA and FDA independently evaluates the information in the EA to determine its acceptability. The Toxicity Report provides summary information from the EA's, identifying the location of the detailed EA reports and FONSI's in the public docket. FDA reviewed the test reports provided in EA's and determined that the methodologies, assumptions, and conclusions of the reports were acceptable. Any interested party may obtain additional information regarding the test methods used for each EA from those reports in the public docket.

Impacts on the environment which result from the incremental impact of an action when added to other past, present, and reasonably foreseeable future actions are known as cumulative impacts. Consideration of cumulative impacts is included in the proposed categorical exclusions for human drugs and biologics. Under § 25.31(a), action on a marketing application for a human drug or biologic or action on an OTC monograph may be categorically excluded if the action does not increase the use of the active moiety. However, if an action increases the use of the active moiety, the impacts of that increased use will require environmental analysis unless the action meets other specific categorical exclusion criteria established in § 25.31(b) and (c). The potential for cumulative effects is also considered in the calculation of the EIC of an active moiety of a drug because the applicant bases these estimates on the expected quantities that will be used 5 years in the future, including the use quantities associated with related FDA applications (see, e.g., Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements, Section III.D.6.e, November 1995).

As stated in the preamble to the proposed rule (61 FR 14922 at 14925, 61 FR 19476 at 19479), one of the criteria for determining that a drug is safe for human use is consideration of its potential to bioaccumulate in body tissue. The vast majority of drugs do not bioaccumulate because that characteristic would raise safety concerns for use of the drugs in humans. If a drug has characteristics that would allow it to bioaccumulate in tissue, the body must have a mechanism to metabolize the compound into a substance that has lower bioaccumulation potential so that it may be cleared from the body. In the EA's that the agency reviewed, bioaccumulation was not an issue.

The practice of using assessment factors in environmental risk assessments is well established. FDA's use of an assessment factor of 1,000 is consistent with EPA's approach (e.g., Zeeman, M., and J. Gilford, ''Ecological Hazard Evaluation and Risk Assessment Under EPA's Toxic Substances Control Act (TSCA): An Introduction,'' in Environmental Toxicology and Risk Assessment, ASTM STP 1179, edited by W. Landis, J. Hughes, and M. Lewis, pp. 7–21, American Society for Testing and Materials, Philadelphia, 1993.).

The toxicity tests performed by FDA applicants and described in the Toxicity Report are consistent with contemporary practice and are based on current scientific thinking. Potential future revision of test methods does not render invalid current testing, data obtained as a result of that testing, or conclusions based on that data.

24. One comment stated that under § 25.31(b), FDA will now apparently permit companies seeking approval of metered dose inhalers to forgo preparation of EA's in connection with their marketing applications. The comment asked that the agency make clear in its final regulations that FDA will require EA's with all applications involving metered dose inhalers that release chlorofluorocarbons (CFC's) and that such EA's must thoroughly evaluate the cumulative impacts of CFC's on the Antarctic environment and alternatives that avoid such impacts.

In 1978, FDA finalized a programmatic EIS regarding the use of fluorocarbons in products subject to regulation by the agency under the act (Final Environmental Impact Statement;

Fluorocarbons: Environmental and Health Implications, February, 1978, Docket No. 76N–0640) and announced the availability of the final EIS in the **Federal Register** (43 FR 11316, March 17, 1978). This EIS was used as the basis for prohibiting use of CFC's as propellants in self-pressurized containers if the use of the CFC was not deemed to be essential. As stated in the EIS:

> The Commissioner of Food and Drugs has concluded that the continued use of chlorofluorocarbon propellants in self-pressurized containers in products subject to the Federal Food, Drug, and Cosmetic Act (FFD&C) poses an unreasonable risk of long-term biological and climatic impacts.
>
> Accordingly, the Food and Drug Administration is finalizing a prohibition of the nonessential use of chlorofluorocarbons as propellants in self-pressurized (aerosolized) containers in products subject to the FFD&C Act. The products to which the regulation applies are human food, food additives, human drugs, including biological products, animal food, animal drugs, cosmetics, and medical devices. (p. iii)

The EIS further stated:

> The selection of fluorocarbon use(s) to be regulated requires a determination of whether or not a particular fluorocarbon use is essential. The Commissioner of Food and Drugs has defined essentiality to mean that there are no technically feasible aerosol or non-aerosol alternatives to using a fluorocarbon in a product and that a product provides a substantial public benefit such as a therapeutic medical benefit. The product need not be indispensable to life, but the benefit must be important and consist of more than added convenience. (p. 89)

A copy of the programmatic EIS has been placed in the administrative record for this rule (Docket No. 96N–0057).

FDA regulations pertaining to the use of CFC propellants in self-pressurized containers are described in § 2.125. CFC's may be used as propellants in a self-pressurized container only if the drug is approved, a petition has been filed as described in § 2.125(f), and § 2.125(e) has been amended to specify the use as essential. The petition requesting an essential use designation must be supported by an adequate showing that: (1) No technically feasible alternatives exist to the use of a CFC in the product; (2) the product provides a substantial health benefit, environmental benefit, or other public benefit that would not be obtainable without the use of the CFC; and (3) the use does not involve a significant release of CFC's into the atmosphere or, in the alternative, the release is warranted in view of the consequences of the use not being permitted. The petition is a public document about which any interested party may comment before a final determination is made by the agency.

FDA is in the process of establishing a policy for determining when uses of CFC's currently designated essential will no longer be deemed essential under the Clean Air Act due to the availability of safe and effective medical product technology that does not use CFC's. (See Docket No. 97N–0023.)

The agency has, in the programmatic EIS, evaluated the individual and cumulative effects, including the effects on human health, stratospheric ozone, biological systems (nonhuman), and climate, of approvals of marketing applications that result in the release of CFC's. FDA has fulfilled its responsibilities and has adequately considered the environmental issues regarding CFC's. Therefore, a requirement that individual marketing applications for metered dose inhalers that release CFC's must include EA's is not necessary because the environmental information would already be under consideration by the agency in its decision whether to designate an essential use under § 2.125(e). Resubmission of this information to the agency would not be consistent with CEQ goals of reducing excessive paperwork. NEPA supplements, but does not supersede, other statutory responsibilities. NEPA establishes requirements to ensure that an agency considers environmental information in its decisionmaking process. Thus, after a review of the relevant environmental information, FDA may, but is not required to, decline to take an action that may have a significant effect on the environment.

25. Proposed § 25.31 lists the general classes of agency actions relating to human drugs and biologics that are categorically excluded and, therefore, ordinarily do not require the preparation of EA's or EIS's. One comment requested that a categorical exclusion be added to the regulations for ''[a]ction on an NDA, abbreviated application, or a supplement to such application, or action on an OTC monograph, if the active moiety has been previously approved by FDA and the concentration in the environment will be above 1 part per billion.''

The agency believes that providing a categorical exclusion in § 25.31 for an active moiety that has been previously approved by the agency is inappropriate. FDA does not have any evidence that actions relating to the approval of a drug or biologic for which the active moiety has been previously approved do not individually or cumulatively have a significant effect on the environment. In some cases, the approval of a new indication or dosage form of a previously approved active moiety could substantially increase the use of the product. In such cases, an EA must be prepared unless the action meets one of the other criteria for a categorical exclusion.

26. One comment requested that proposed § 25.31 be revised to add a categorical exclusion for actions relating to drugs that involve substances that have an environmental concentration greater than 1 ppb (i.e., do not meet the criteria for categorical exclusion under § 25.31(b)) but have a PEC to a predicted no effects concentration (PNEC) ratio equaling less than one.

The agency declines to amend § 25.31 as requested. A PEC/PNEC ratio is one of several commonly used approaches for evaluating environmental effects. To calculate the PEC/PNEC ratio, ecotoxicity studies are performed, results are compared to expected environmental concentrations, and a conclusion is drawn. The calculation also requires use of an assessment factor that will vary depending on the type of ecotoxicity data generated. The PEC/PNEC ratio constitutes an environmental analysis and, therefore, is not an appropriate criterion for a categorical exclusion. If FDA were to use a PEC/PNEC ratio as a criterion for categorical exclusion, FDA would need to review the underlying data that supports the PEC/PNEC ratio, including the assessment factor, and would, in essence, be requiring an EA. Thus, FDA will not add a categorical exclusion for actions relating to drugs based on the calculation of a PEC/PNEC ratio. An applicant is not precluded, however, from using a PEC/PNEC ratio to assess environmental effects in an EA or to aid in determining whether extraordinary circumstances exist such that a proposed action, which is normally excluded, may have an environmental effect.

27. One comment recommended that the categorical exclusion described in proposed § 25.31(c) for naturally occurring substances not include new steroid or hormone modulating drugs.

As explained in the preamble to the proposal (61 FR 14922 at 14926, 61 FR 19476 at 19480), FDA based the categorical exclusion in § 25.31(c) on its finding, after reviewing abbreviated EA's for substances that are naturally occurring, that actions on submissions for these substances will not affect the environment if the action will not significantly alter the concentration or distribution of the natural substance in the environment. No information was provided in the comment to support the need for this change. The available

evidence does not support a finding that new steroid or hormone modulating drugs, at the expected level of exposure, have the potential to significantly affect the environment. Therefore FDA will not modify § 25.31(c). The agency specifically addressed concerns regarding synthetic estrogens used in human drugs in comment 16 of this document. The agency will evaluate each proposed action on an individual basis to determine if extraordinary circumstances exist such that further environmental documentation is needed.

28. One comment requested clarification regarding the definition of ''substances that occur naturally in the environment'' as that phrase is used in proposed § 25.31(c). The comment suggested that the categorical exclusion be revised to read ''substances that either occur naturally in the environment, or are derived from biological systems'' or, alternatively, that FDA provide a definition in the regulation.

The agency declines to adopt the language suggested in the comment because the term ''or derived from biological systems'' is too broad. Not all substances produced by a biological system may be substances that occur naturally in the environment. The biological system, or the substance itself, may be modified such that the substance does not occur naturally in the environment. The comment provided no rationale as to why biologically-derived substances not occurring naturally in the environment should be subject to the categorical exclusion.

FDA intends to clarify which type of actions would fall under this categorical exclusion in guidance documents prepared by each center. FDA-regulated articles may be considered for categorical exclusion under this provision whether they are obtained from natural sources, biological systems, or are chemically synthesized. The agency will consider the form in which the FDA-regulated article will exist in the environment when determining if an action will be eligible for this categorical exclusion. For example, a modified active moiety (e.g., salt) which does not occur naturally may be considered a naturally occurring substance if it is established that, in vivo and in the environment, the active moiety exists in a form that is found naturally. Biological and biotechnological products will be similarly evaluated. For example, a protein or DNA comprised of naturally occurring amino acids or nucleosides, but with a sequence different from that of a naturally occurring substance, will normally qualify for this categorical exclusion after consideration of metabolism. The same principle will apply to synthetic peptides and oligonucleotides. Living and dead cells and organisms regulated by the agency may also be considered for categorical exclusion under this provision if the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. The agency will rely on the significant amount of information submitted by an applicant in support of a requested action (for example information about metabolism, excretion, and stability; viability (if applicable); and physical/chemical characteristics of the product) in determining whether categorical exclusion under § 25.31(c) is appropriate.

29. One comment requested that the phrase ''action on an OTC monograph,'' which is included in the categorical exclusions in § 25.31 (a), (b), and (c), be changed to ''OTC activity'' and that the regulation define ''OTC activity'' as ''an action on an OTC monograph or a switch of a drug from prescription to OTC use that is submitted in an NDA or supplement, if the product is already marketed for the proposed use.'' The comment expressed a belief that the preamble to the proposed rule ''is clear on the intent for a prescription to an OTC switch to be considered as a categorical exclusion.''

FDA does not believe it is necessary or appropriate to substitute ''OTC activity'' for ''action on an OTC monograph'' in § 25.31 (a), (b), and (c). Agency action on any request to switch a drug from prescription to OTC use is already covered in § 25.31 (a), (b), and (c) by the language ''action on an NDA, abbreviated application, or a supplement to such application, or action on an OTC monograph.'' Depending on the circumstances and the applicant's preference, a prescription to OTC switch may be requested using any of these administrative filing mechanisms. As discussed in the preamble (61 FR 14922 at 14925, 61 FR 19476 at 19479), the agency will not elevate form over substance and will treat like actions alike, regardless of the avenue through which the actions are requested. Thus, the same categorical exclusion criteria will apply to NDA's, abbreviated applications, supplements, and ''actions on OTC monographs.''

Prescription to OTC switches have generally been, and will continue to be, considered by CDER to be actions that increase use because the potential patient population expands from only those persons who seek treatment under a physician's care to any person who enters a retail establishment that sells OTC products. Therefore, agency action on an OTC switch will be categorically excluded if the criteria of § 25.31 (b) or (c) apply to the action, specifically if the concentration of the substance at the point of entry into the aquatic environment will be below 1 ppb (§ 25.31(b)), or if it is a substance that occurs naturally in the environment and the action will not significantly alter the concentration of the substance in the environment (§ 25.31(c)).

30. Proposed § 25.31(e) would categorically exclude action on an IND from the requirement to prepare an EA. One comment suggested that this exclusion be limited by specifying in the exclusion a ceiling on the quantity (number of doses) to be released into the environment.

As stated in the preamble to the proposed rule (61 FR 14922 at 14926, 61 FR 19476 at 19480), FDA action on an IND in many cases does not significantly increase the use of the drug or the amount of the drug introduced into the environment because the drug is being administered to few patients or is already being marketed for another use. Consequently, no changes in the effect on the environment will occur due to agency action on the IND. In the event FDA action on an IND would increase the use of a drug, the agency's experience has demonstrated that significant environmental effects would not occur because the investigational use is limited and controlled. The dosing regimen for investigational drugs that would result in an environmental introduction concentration of 1 ppb (the concentration below which FDA has found no significant effect on the environment) is not expected for clinical trials held under an IND. Very large clinical trials are rare, but, cumulatively, they enroll approximately 8,000 patients. Those subjects would need to use 14 grams of the active moiety every day for an entire year to result in an environmental introduction concentration of approximately 1 ppb, the concentration below which CDER has routinely observed no significant effects on relevant standard test organisms in the aquatic environment. The level and duration of this dosing regimen, as described, are greater than is expected under clinical trials, thus the addition of a criterion limiting the number of doses is unnecessary.

The preamble to the proposed rule (61 FR 14922 at 14923, 61 FR 19476 at 19477) noted that categorical exclusion

criteria relating to toxicity, which includes current § 25.24(c)(4), ''if * * * waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic,'' have been incorporated into the extraordinary circumstances provision of § 25.21(a). Therefore, the categorical exclusion for IND's remains essentially unchanged. In the event FDA has reason to believe its action on an IND may significantly affect the environment, FDA will invoke the provision relating to ''extraordinary circumstances'' and require an EA. Therefore, the agency declines the suggestion to modify the categorical exclusion in § 25.31(e).

2. Foods, Food Additives, and Color Additives

31. Proposed § 25.32(b) provides for a categorical exclusion for FDA action on a request for exemption for investigational use of a food additive, if the food additive is intended to be used for clinical studies or research. One comment noted the absence of a discussion concerning the potential impact of the investigational use of food additives in the preamble to the proposal, despite the discussion about the potential environmental impact of investigational and clinical research for drugs. The comment recommended that FDA establish a maximum annual quantity for investigational uses of food additives allowed to be released to the environment.

The agency declines to establish additional criteria for the application of the categorical exclusion of the investigational use of food additives. FDA has not required that a formal application be submitted to the agency for the investigational use of a food additive. The investigational use of food additives is expected to be limited to small amounts needed in studies with laboratory animals under 21 CFR 170.17. Occasionally additives are tested in limited clinical trials under the control of institutional review boards. The program has functioned for 40 years with little investigational activity under 21 U.S.C. 348(i). Thus, the agency is not aware of any need to revise this exclusion to include a ceiling on the yearly amount of a substance that may be released into the environment. Furthermore, the comment provided no information on which to conclude that such a ceiling is justified.

32. One comment specifically supported the categorical exclusions in the proposed rule for food and color additives and generally recognized as safe (GRAS) substances. Another comment specifically supported the categorical exclusions set forth in proposed § 25.32 (i), (k), and (r), but raised issues regarding the need for reform of the review process for food additive and GRAS petitions.

Reform of the review process for food additive and GRAS petitions is outside the scope of this rulemaking and will not be addressed here.

33. One comment, while generally supporting the categorical exclusions in proposed § 25.32 (i) and (j), requested that they be expanded to include all actions on components of food-contact materials, including actions on GRAS petitions, except where extraordinary circumstances exist. The comment asserted that compiling the information needed for EA's for food-packaging materials is unnecessary and unduly burdensome, that the costs of preparing EA's for these materials are significant, and that routine preparation of EA's for these actions results in an unnecessary expenditure of industry and agency resources. The comment requested that the agency not require EA's for actions on nonfunctional components of food-packaging materials because Federal, State, and local laws and regulations adequately control emissions to the environment at sites where these substances are used in the manufacture of food-packaging materials. The comment pointed out that the agency is proposing not to require information on the production of FDA-regulated substances based on its recognition that Federal, State, and local environmental laws and regulations adequately protect the environment at the production sites for those substances. The comment requested that the agency apply the same reasoning to conclude that EA's are no longer needed to assess the environmental impact of nonfunctional components of food-packaging materials that are used and enter the environment at the production sites of the packaging material. The comment also requested that EA's not be required for actions involving components of finished food-packaging material present at greater than 5 percent-by-weight because: (1) Most of these additives will replace other similar, already regulated additives and will not have any meaningful impact on the potential uses of the finished food-packaging material; and (2) adequate Federal, State, and local laws and regulations are in place to protect environments that may be affected by disposal of food-packaging material. The comment pointed out that ''in certain rare situations, for example, in instances where the use of a new material may affect recycling streams, disposal of food-packaging materials prepared from a newly regulated polymer could potentially have some effect on the environment.'' The comment suggested that in these instances it may be appropriate for the agency to require an EA and that proposed § 25.21 (Extraordinary circumstances) will provide the agency with the means to require EA's for these few situations.

FDA agrees that the new categorical exclusions in proposed § 25.32 (i) and (j) should be revised to include GRAS petitions. The agency also acknowledges that there are certain classes of nonfunctional components of food-packaging materials and certain classes of components of food-packaging material present at greater than 5 percent-by-weight of the finished food-packaging material that should be included under § 25.32(i). However, FDA does not agree that all classes of actions on substances intended for use as components of food-contact materials warrant categorical exclusion. Nor does the agency agree that compiling the information needed for EA's for food-packaging materials is unnecessary, unduly burdensome, and costly. The basis for the agency's decision on these classes of actions is explained below.

GRAS petitions: None of the petitions that the agency has reviewed while developing the categorical exclusions in § 25.32 (i) and (j) (including those it has reviewed since the proposal issued) were GRAS affirmation petitions for components of food-packaging material or components of food-contact surfaces of equipment or other repeat use food-contact articles. But, because the environmental information that would be needed under part 25 for a GRAS petition for these types of food-contact substances is identical to the information required for a food additive petition, the agency believes that its experience with food additive petitions is relevant to GRAS affirmation petitions and that any future GRAS affirmation petitions for these classes of actions can also be excluded. Therefore, FDA has revised proposed § 25.32(i) and (j) to include actions on GRAS affirmation petitions.

Nonfunctional components of food-packaging material: The agency does not believe it is appropriate to categorically exclude all actions on nonfunctional components of food-packaging material, as requested by the comment. To evaluate the request that FDA revise § 25.32(i) to further exclude from the requirements for EA actions on nonfunctional components of food-packaging materials, the agency reviewed 44 petitions for nonfunctional components of food-packaging

materials.[1] As a result of this review, the agency found that a number of these petitions warranted exclusion from the need for an EA, while others did not. The agency found that 13 of the petitions were for additives that remained with food-packaging materials used by consumers despite the fact that these additives did not function in the finished food-packaging material. As they pertained to use and disposal of nonfunctional components of food-packaging materials, the FONSI's for the agency's actions on these petitions were based on the following factors: (1) Only very small quantities, if any, of these additives were expected to enter the environment at sites where the additives were used in the manufacture of food-packaging materials; (2) only extremely low levels of substances, if any, could be expected to enter the environment as a result of disposal of food-packaging materials; and (3) virtually no change in the use of natural resources and energy would be expected because the additives would be replacing other, currently regulated, additives and would not affect the uses of the packaging materials to which they were added. These factors are the same as those upon which the agency bases its exclusion for actions on functional components of finished food-packaging materials. Therefore, the agency has decided that it is appropriate to revise proposed § 25.32(i) to include all components of food-packaging materials that remain with finished packaging through use by consumers and are present at less than 5 percent-by-weight, regardless of whether they perform a function in the finished package.

In its review of the remaining 31 petitions involving nonfunctional components of finished food-packaging material, the agency found that 5 petitions were for antimicrobial substances that are also regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as pesticides. In § 25.32(q) of the proposed rule, actions to approve a food additive petition or grant a request for exemption from regulation as a food additive under § 170.39 are categorically excluded when the substance that is the subject of the petition or request is registered by EPA under FIFRA for the same use requested in the petition or in the request for exemption.

Also among these 31 petitions were 6 petitions for substances that occur naturally in the environment. These petitions would be excluded from the requirement to prepare an EA under the categorical exclusion in § 25.32(r) of the final rule.

The 20 remaining petitions involving nonfunctional components of finished food-packaging material were for additives that were not expected to remain with the finished article, but instead were expected to enter the environment at sites where they were used as processing aids in the manufacture of food-packaging materials and were neither antimicrobial substances nor naturally occurring substances. These types of additives are not intended to remain with the finished food-packaging materials which are used and disposed of by consumers throughout the United States. The results of environmental toxicity tests presented in some of these petitions showed that the additives had the potential to harm organisms in the environment present at or adjacent to the use sites. For 17 of these 20 petitions, FDA conducted an analysis of the environmental exposure levels of the additives at the use sites and compared these exposure levels to environmental toxicity information on the additives to determine the potential for significant impact. In some cases, the margin between environmental exposure levels and levels found to be toxic to organisms present in the receiving environment was very narrow. For the remaining three petitions, FDA relied upon adequate regulation of potential discharges to reach its environmental decision.

Under current part 25, FDA has required specific information about Federal, State, and local laws and regulations that are applicable to emissions at the site of production of the subject substances where the manufacturing operations are designed to provide maximum yield of the FDA-regulated article for commercial sale. FDA reviewed hundreds of submissions with this information before deciding to eliminate the requirements for its inclusion. However, the formats for EA's in current § 25.31a do not require information on emissions requirements at the sites where nonfunctional components of food-packaging materials are used to produce the finished article. A review of FDA's experience with EA's for most nonfunctional components of finished food-packaging materials that are expected to enter the localized use site environment (i.e., the finished food-packaging manufacturing facility) has revealed that analysis of exposure and environmental toxicity is necessary to determine the potential for significant impact. Based on this experience, therefore, the agency does not agree with the comment that it can rely on other Federal, State, and local laws for protecting the environment to exclude actions on petitions for these nonfunctional components of food-packaging materials as was done to eliminate requirements for information on the sites of production of FDA-regulated articles.

Thus, the agency cannot establish an additional categorical exclusion for petitions for nonfunctional components of food-packaging that do not remain with food-packaging through use by consumers. The agency will provide specific guidance to petitioners for preparing EA's for those categories of petitions that will require EA preparation. The guidance for EA's involving nonfunctional components of food-packaging materials will focus on the relevant issues surrounding a proposed action and will take into consideration whether other laws and regulations adequately control potential environmental impacts or whether an action may threaten a violation of such laws and regulations as required by CEQ regulations (40 CFR 1508.27(b)(10)).

Components of Finished Food-packaging Material Present at Greater than 5 Percent-by-Weight: The comment requested a categorical exclusion for actions involving components of finished food-packaging material present at greater than 5 percent-by-weight, but did not provide any specific information showing that actions on petitions in this category do not individually or cumulatively have significant environmental effects. To evaluate this request, FDA reviewed 30 petitions for components of food-packaging materials present at greater than 5 percent.[2] The agency found that five of these petitions were for coatings or components of coatings for food-packaging materials. The FONSI's for the agency's actions on these petitions were based on the following factors: (1) Only extremely low levels of substances, if any, could be expected to enter the environment as a result of use and disposal of these coated food-packaging materials; and (2) virtually no change in the use of natural resources and energy would occur because the additives would be replacing other, currently regulated, additives and would not affect either the uses of the packaging materials to which they were added or the disposal technologies used for these materials. These factors are the same as those upon which the exclusion for actions on functional components of

[1] ''Index of Petitions for Nonfunctional Components of Food-packaging Materials,'' (Docket No. 96N–0057).

[2] ''Index of Petitions for Components of Food-packaging Materials Present at Greater than 5%,'' (Docket No. 96N–0057).

finished food-packaging materials present at less than 5 percent are based even though the components of the coatings may be present in the finished food-packaging material at greater than 5 percent-by-weight. Therefore, the agency is revising the exclusion in proposed § 25.32(i) to include actions on the components of coatings of finished food-packaging materials.

The agency's findings for the remaining 25 petitions support FDA's position that significant environmental effects may result from agency actions on components of finished food-packaging material present at greater than 5 percent-by-weight. Examples of petitions that required extensive analysis to determine the potential impact of food-packaging materials on solid waste management strategies include food additive petition (FAP) 6B3948 (Docket No. 86F–0341); FAP 7B3979 (Docket No. 86F–0508); FAP 8B4107 (Docket No. 88F–0404); FAP 1B4236 (Docket No. 91F–0198); and FAP 8B4110 (Docket No. 88F–0339). In some cases, the agency and the petitioners decided to include mitigating measures in the food additive regulations to avoid potentially significant environmental effects. In addition, the agency has not acted on FAP 7B3994, because it needs to consider further whether significant effects on solid waste management strategies may result (53 FR 47264 at 47267, November 22, 1988). Evaluation of these potential effects is being conducted along with an evaluation of the agency's proposed action to provide for the safe use of vinyl chloride polymers (51 FR 4177, February 3, 1986). The agency announced on November 22, 1988 (53 FR 47264), its intent to prepare an EIS on its actions on vinyl chloride and other chlorinated polymers. FDA continues to work on this statement.

This comment asserted that EA's are not needed for petitions for components of food-packaging materials because the effects of disposal of food-packaging materials by incineration or landfilling are subject to the control of laws, regulations, and government authorities directly concerned with the environment. FDA, based on its experience, agrees that the extremely low levels of substances that may leach from food-packaging materials disposed of in landfills are adequately controlled by EPA regulations in 40 CFR part 258. FDA is aware of laws and regulations governing the incineration of municipal solid waste, which include the incineration of food-packaging materials. However, there is potential for incineration of food-packaging materials to threaten a violation of these laws and regulations. FDA will consider this potential effect under 40 CFR 1508.27(b)(10). For example, in its decision to prepare an EIS on its actions on vinyl chloride and other chlorinated polymers (53 FR 47264 at 47265, November 22, 1988), the agency found that the expected increase in hydrogen chloride emissions from incinerators may affect the ability of incinerator operators to comply with existing and anticipated emissions standards. This issue is still under agency review.

A number of the agency's actions on components of food-packaging materials present at greater than 5 percent-by-weight had potential for significant effects on the environment. The agency is unable, without specific information such as that provided in an EA, to distinguish which petitions for these actions may have potential for significant impact. Therefore, the agency will continue to require EA's for this category of petitions, with the exception of those petitions pertaining to components of coatings. The agency will develop and provide to petitioners specific guidance for preparing EA's for those categories of petitions that will require the preparation of EA's. The guidance for EA's involving components of packaging present at greater than 5 percent-by-weight will focus on the relevant issues surrounding a proposed action, and will take into consideration the extent to which other laws and regulations adequately control potential environmental impacts.

As a result of this analysis, proposed § 25.32, categorical exclusions for foods, food additives, and color additives, will be revised at paragraphs (i) and (j) to read as follows:

(i) Approval of a food additive petition, GRAS affirmation petition, or the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, when the substance is present in finished food-packaging material at not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material.

(j) Approval of a food additive petition, GRAS affirmation petition, or the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, when the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

Burden of compiling the information for EA's for food-packaging materials: As discussed above, for certain actions involving food-packaging materials, FDA will continue to require petitioners to submit an EA. FDA does not agree that the information it requires the petitioner to submit in these EA's is unnecessary, nor does the agency believe the effort to provide such information is unduly burdensome. As FDA has stated above, it will provide guidance to industry regarding the focus of environmental documents. In addition, FDA has limited in the past and will continue to limit its requests for information to only the amount needed to assess the potential environmental impact of its actions. FDA recognizes that in some cases the information needed for EA's is not readily available or is not yet known to a petitioner. In such cases, the agency in the past has asked the petitioner to provide a best possible forecast or to use a conservative approach to analyze environmental effects. FDA will continue this approach, recognizing that in some cases there may be uncertainty about the potential for significant environmental impact of food-packaging materials.

In the preamble to the proposal (61 FR 14922 at 14935, 61 FR 19476 at 19489), FDA noted its calculation that the proposed changes in the environmental regulations would reduce the costs for both the regulated industry and for the agency. These reduced costs will result from, among other things, providing for categorical exclusions for additional classes of actions. To this end, the agency proposed and is now making final two exclusions that will apply to actions on food-packaging materials (§ 25.32 (i) and (j)). As explained above, these exclusions have been expanded in the final rule to include additional classes of actions. These changes are expected to further reduce the costs of preparing and reviewing environmental documents for food-packaging materials. The agency believes that the remaining actions on food-packaging materials that require EA's have the potential to result in significant environmental effects, and information in an EA is necessary for the agency to make decisions on these potential effects.

34. Proposed § 25.32(k) would categorically exclude actions to approve food additive, color additive, and GRAS affirmation petitions for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in foods. One comment claimed that FDA was proposing a 1 ppb environmental exposure threshold below which the exclusion applied, as was done for human drugs in proposed § 25.31(b). The comment requested that FDA establish a maximum annual quantity of

the food additive allowed to be released to the environment under this exclusion.

The agency declines to establish additional criteria for the exclusion under § 25.32(k) covering substances that are intended to remain in food through ingestion by consumers and are not intended to replace macronutrients in food. As explained in the preamble to the proposal (61 FR 14922 at 14928, 61 FR 19476 at 19482), the basis for this exclusion is FDA's experience reviewing 21 petitions in this class, all of which resulted in a FONSI. The FONSI's relied on one or more of the following scenarios: (1) The approval of the petition resulted in very low levels of the substances in either effluents and/or sewage sludge; (2) the substance was digested and/or metabolized by humans such that only the products of digestion and metabolism were expected to be excreted and those products were the same as (or very similar to) other products of digestion and metabolism resulting from human food; or (3) the substance was excreted largely intact but was rapidly degraded into nontoxic products. Based upon this review of petitions in this class, the agency found that it was not necessary to establish either an exposure threshold concentration or a maximum annual quantity of substances allowed to be released. Even in the three instances where it was necessary to compare the environmental exposure level of the substance with environmental toxicity data, there was a wide margin of safety. No information to support the establishment of either of these qualifying thresholds is provided in the comment. Therefore, the agency has no basis on which to revise § 25.32(k) to incorporate either an exposure threshold concentration or a maximum annual quantity that may be released.

35. An additional comment about the exclusion in proposed § 25.32(k) expressed concern about the potential for significant impacts on energy and natural resources resulting from the use and disposal of nonnutritive oils. This comment recommended that the proposed exclusion be withdrawn or that a ceiling be added that would require an EA where such substances enter the environment above a certain annual level.

The agency declines to amend the proposed exclusion as recommended. Actions on food additive petitions for nonnutritive oils or fat substitutes would not qualify for the categorical exclusion in § 25.32(k), because such substances are considered to be replacements for macronutrients. An EA submitted for a fat substitute would include consideration of the impact on energy and natural resources resulting from the production (if appropriate), use, and disposal of such substances. Such considerations were part of FDA's action to approve the use of the fat substitute olestra (Docket No. 87F–0179).

36. Proposed § 25.32(m) would categorically exclude actions to prohibit or otherwise restrict or reduce the use of asubstance in food, food packaging, or cosmetics. One comment supported this exclusion, but requested clarification regarding how FDA will consider under this exclusion impacts on the environment (to human well-being and on the environment itself) that are controversial.

As discussed in the preamble to the proposal (61 FR 14922 at 14929, 61 FR 19476 at 19483), the agency has found that this class of actions has not involved controversial issues with respect to potential impact on the physical environment. FDA's action to prohibit the use of CFC's is the only exception to this principle to date.

In most instances, the purpose of actions to restrict or withdraw approval of foods, food packaging, or cosmetics is to protect the public health. Potential impacts on human health, and any controversy surrounding such impacts, are fully considered in **Federal Register** documents (e.g., a preamble to a proposed or final rule restricting or withdrawing approval) supporting the action. See the response to comment 22, above. The appropriateness of an exclusion for a proposed action to restrict or eliminate the use of a substance in food, food-packaging, or cosmetics will depend on whether the action may involve extraordinary circumstances that would require evaluation through an EA or an EIS. Under proposed § 25.21, extraordinary circumstances include the degree to which the possible effects on the human environment are likely to be highly controversial, as provided in 40 CFR 1508.27(b)(4).

37. Proposed § 25.32(o) would categorically exclude actions to approve a food additive petition for the intended expression product(s) present in food derived from new plant varieties. One comment recommended that compounds that may be ''hormone modulators'' should not be included in this categorical exclusion.

FDA is not aware of any specific substances derived from new plant varieties that could potentially affect the endocrine system of other organisms. It is unlikely that FDA would receive a food additive petition for a substance derived from new plant varieties that was intended to have a physiological effect on the human endocrine system. A substance derived from new plant varieties that is intended to have such an effect on the human endocrine system would be regulated by FDA as a drug. Thus, it is unlikely that a claim for categorical exclusion for a hormone modulator would be made under § 25.32(o) and FDA declines to modify § 25.32(o) to reflect such a scenario.

In the event FDA receives a food additive petition for a substance derived from new plant varieties that is known or suspected to have potential for affecting the endocrine system in humans, aquatic life, and/or wildlife, agency action on such a petition would generally be excluded under § 25.32(o). As described in the preamble to the proposed rule (61 FR 14922 at 14929–14930, 61 FR 19476 at 19483–19484), under § 25.32(o) environmental review of new plant varieties would be performed by the United States Department of Agriculture (USDA). Therefore, if USDA has granted a categorical exclusion or conducted an environmental review, NEPA review by FDA would be redundant and therefore, unnecessary.

38. In proposed § 25.32(q), actions to approve a food additive petition or grant a request for exemption from regulation as a food additive under § 170.39 are categorically excluded when the substance that is the subject of the petition or request is registered by EPA under FIFRA for the same use requested in the petition or in the request for exemption. One comment stated that the same information submitted to EPA for registration of pesticides under FIFRA should be encouraged for FDA submissions. The comment expressed concern about the lack of policy alignment between agencies regarding the level of risk and about the ability of FDA to meet deadlines due to its reliance on the review of data by another agency that may have different review priorities. The comment suggested that FDA ''handle this proposed exclusion as a guideline policy rather than a categorical exclusion,'' or align interagency risk determination policies before allowing this exclusion.

FDA does not agree with the suggestion that the exclusion be handled as a guideline policy. As discussed in the preamble to the proposal (61 FR 14922 at 14930, 61 FR 19476 at 19484), FDA has found that the scope of EPA's review of the environmental risk of antimicrobial substances subject to pesticide registration under FIFRA encompasses FDA's review of the environmental risk

of these substances for food additive use under NEPA. In evaluating whether a food additive petition or request for exemption meets the categorical exclusion in § 25.32(q), FDA will ensure that the substance for which a petitioner seeks approval is identical to the substance that is registered as a pesticide under FIFRA. If the substance is registered as part of a formulation under FIFRA, FDA will ensure that it is approving the substance for use as part of that formulation registered under FIFRA. By ''same use'' the agency means that in a comparison of the food additive use to the pesticide use, the purpose of the use, any components used with the substance for the petitioned use, and the amount of the substance and the amounts of any components used with it are substantially identical. FDA has found that, when these antimicrobial substances are intended for the same use, its assessment of the environmental risk of antimicrobial substances is the same as EPA's assessment of the environmental risk of pesticides and, therefore, the food additive use will be subsumed under EPA's environmental review of the substance as a pesticide registered under FIFRA.

In addition to ensuring that the substance is identical to and for the same use as the registered pesticide, FDA will ensure that the label for the use of the substance as a food additive includes information related to the environmental effects, such as precautionary statements on environmental hazards, that is required on the label for the use of the substance as a registered pesticide under FIFRA. This will provide assurance that any adverse environmental effects from the use of the substance as a food additive have been addressed and are mitigated, as needed, to the same extent as any adverse environmental effects from the use of the substance as a pesticide registered under FIFRA.

In response to the comment that FDA may not be able to meet its deadlines because of its reliance on review of data by another agency, nothing in this final rule precludes a petitioner or requester from submitting an environmental assessment to FDA for review, despite the fact that the action may be eligible for a categorical exclusion under § 25.32(q). Moreover, establishing a categorical exclusion for an antimicrobial substance that is registered as a pesticide with EPA under FIFRA should not affect FDA's ability to meet its statutory deadlines for completing the review of food additive petitions that are eligible for an exclusion under § 25.32(q). In order for a substance to be eligible for a § 25.32(q) categorical exclusion, the substance must be registered by EPA as a pesticide under FIFRA for the same use requested in the petition at the time the food additive petition is submitted to FDA. Antimicrobial substances that are not registered by EPA under FIFRA for the same use at the time the food additive petition is submitted to FDA would not be eligible for a categorical exclusion under § 25.32(q). Without the pesticide registration, FDA would not be able to determine whether the use is the same as that in the food additive petition or request for exemption and therefore eligible for a categorical exclusion.

As previously mentioned, the scope of environmental review for a pesticide registration, based on the agency's review of previous petitions, encompasses FDA's environmental review for the use of the substance as a food additive. Therefore, the agency does not anticipate that any additional environmental review would be required for a petitioned food additive use of a substance that is registered as a pesticide under FIFRA. However, if the substance is not registered as a pesticide under FIFRA or the environmental impacts resulting from the petitioned food additive use or request for exemption are not within the scope of EPA's environmental assessment performed for the pesticide registration, FDA's action on the substance would not warrant categorical exclusion under § 25.32(q), and instead, would require at least an EA under § 25.20.

3. Veterinary Drugs and Feed Additives

39. Proposed § 25.33(a) would categorically exclude action on an NADA, abbreviated application, or supplement to such applications, if the action does not increase the use of the drug. One comment pointed out that, in its categorical exclusion relating to actions that do not increase use, FDA uses the term ''active moiety'' when referring to human drugs in proposed § 25.31(a) and ''drug'' when referring to animal drugs in proposed § 25.33(a). The comment stated that the reason for the use of different terms was not apparent, and recommended that the term active moiety also be used when referring both to human drugs and animal drugs.

The agency does not agree that the term ''active moiety'' should be used in § 25.33(a) to describe the actions on animal drugs that are categorically excluded because for many animal drugs an explicit active moiety cannot be defined. For example, an animal drug may consist of biomass which is the purified broth from fermentation manufacturing. In that case, the animal drug consists of a variety of components but an ''active moiety'' is not explicitly defined. If there is no increase in the use of an animal drug, it follows that there is no increase in the level of the substance in the environment and, consequently, no increase in any associated environmental effects.

40. One comment requested that proposed § 25.33(a) be revised to categorically exclude actions that do not increase the use and the concentration of the drug. The comment reasoned that when an animal drug is administered, the concentration of that drug in the environment, rather than the fact of ''use,'' has the potential to raise environmental concerns.

The agency agrees that an increase in concentration has the potential to raise environmental concern but does not agree that the addition of the term ''increase concentration'' to the exclusion is necessary. The primary purpose of the categorical exclusion is to provide a simple method to identify for drug sponsors which actions obviously have no significant environmental impacts. An increase in use, such as an increase in dosage level, an increase in the duration of use, or the addition of a new indication obviously results in an increase in the environmental concentration. To help clarify what actions are categorically excluded under proposed § 25.33(a), the agency has defined in proposed § 25.5(b)(4) that ''increased use'' may occur if the drug is administered at higher dosage levels, for longer duration, or for different indications than were previously in effect, and if the drug is a new molecular entity. The term ''use'' is further defined to encompass disposal of FDA-related articles. Section 25.33(a) also lists specific examples of the actions that are excluded. Therefore, the agency believes that the use of the term ''increased use,'' as defined in § 25.5(b)(4), along with the examples provided, best describes the criteria for categorical exclusion under proposed § 25.33(a).

41. In proposed § 25.33(a), change in sponsor is included as one of the types of actions covered by the categorical exclusion (§ 25.33(a)(5)). One comment requested that FDA reconsider the inclusion of actions relating to changes in drug sponsors in this categorical exclusion because such a change may result in manufacturing or process changes that could cause a difference in end product chemical profiles. The comment argued that differences in manufacturing practices may warrant further environmental evaluation.

The agency reconsidered the proposed categorical exclusion for changes in drug sponsor but decided to retain the exclusion in the final rule. A change in sponsor does not necessarily involve a change in the manufacturing or processing of a drug. In the event that a change in sponsor results in manufacturing or process changes, it is not likely that there will be a change in the end product that will affect the environmental impacts of the drug because a new sponsor must maintain the same quality, composition, and purity of the drug to assure that its safety and effectiveness are the same as the product approved for manufacture by a previous sponsor. Any change that would result in a change in the chemical profile of the end product would require a supplement to be filed with the agency. The need for environmental information would be evaluated by FDA in conjunction with agency action on that supplement. The exclusion in § 25.33(a) has been changed to clarify that actions listed ''may'' be excluded if the actions meet the criteria in the categorical exclusion.

42. In the preamble to FDA's proposed regulations (61 FR 14922 at 14931, 61 FR 19476 at 19485), FDA stated that proposed § 25.33(b) is being reserved for animal drugs ''not otherwise excluded in § 25.33(a).'' One comment expressed concern that this statement regarding § 25.33(b) may inadvertently create confusion about the actions on animal drugs exclusions in other paragraphs of proposed § 25.33, especially in proposed § 25.33(d)(5).

FDA can understand how the wording in the preamble (61 FR 14922 at 14931 and 14932, 61 FR 19476 at 19485 and 19486) could be confusing, but the regulations are explicit about what actions are categorically excluded. Actions that do not meet the criteria of § 25.33(a) may still be categorically excluded under § 25.33 (c) or (d), including § 25.33(d)(5). If the agency adopts criteria for excluding actions under § 25.33(b) as discussed in the preamble, this will add additional criteria for excluding actions, it will not restrict the application of other criteria to exclude actions.

43. One comment suggested that reserved § 25.33(b) should categorically exclude any action on an NADA, abbreviated application, or a supplement to such applications, that increases the use of a drug if the PEC in soil is less than the PNEC, based on a scientifically valid environmental test conducted with a representative soil organism. The comment noted that a relatively simple scientific explanation or calculation would be needed to determine whether an action qualifies for such an exclusion. The comment defended the use of a scientific threshold or screening test for a categorical exclusion as appropriate, citing regulations issued by the Bureau of Indian Affairs (BIA), EPA, and the Federal Highway Administration (FHWA).

The agency declines to revise the proposed regulations as suggested. As explained above, the agency stated in the preamble to the proposal that it was reserving § 25.33(b) to provide for actions that increase the use of an animal drug when the agency determines a level at or below which the concentration of the substance in the environment does not significantly affect the environment. Criteria for this categorical exclusion would require a relatively simple calculation using limited available information. The proposed PEC to PNEC comparison represents more than a simple calculation or explanation. Ecotoxicity studies are performed, results are compared to expected environmental concentrations, and a conclusion is drawn (see the response to comment 26). The agency considers this activity to be an environmental risk assessment that is more appropriately provided as part of an EA.

The agency reviewed the BIA, EPA, and FHWA regulations cited in the comment. The BIA categorical exclusion refers to standards that are required by the Bureau of Land Management (BLM). To qualify for this categorical exclusion, an applicant merely states that it is in compliance with the BLM requirements. No scientific threshold or screening test is required. The EPA and FHWA citations refer to EPA and FHWA general categorical exclusion processes and do not include scientific explanations or calculations.

44. One comment addressed its statements to FDA's description, in the preamble to the proposal (61 FR 14922 at 14931, 61 FR 19476 at 19485), of the categorical exclusions established in proposed § 25.33 (a) and (b). The comment stated that the EIC, rather than the EEC, should be used to determine potential environmental impacts of veterinary drugs and feed additives. The comment argued that this will give more weight in determining potential exposures to ''primary receptors'' before environmental degradation or waste treatment. The comment also recommended that the evaluation should include potential human exposure, such as the potential exposure to children assisting in animal care or living in close proximity to family farm feedlots, at the EIC.

As explained above in response to comment 43 and in the preamble to the proposed rule (61 FR 14922 at 14931, 61 FR 19476 at 19485), § 25.33(a) categorically excludes action on an NADA, abbreviated application, or supplement to such applications, if the action does not increase the use of the drug. Proposed § 25.33(b) is reserved and would be for actions that increase the use of an animal drug if the agency determines a level at or below which the concentration of the substance in the environment does not significantly affect the environment.

The EEC is an appropriate measure to use in evaluating information in an EA to determine whether an environmental impact is expected. The EEC provides the most accurate means of determining the concentration of a substance to which organisms may be exposed. Due to various factors in the environment, e.g., dilution, binding to particulate matter, and volatility, the concentration of an introduced compound may change significantly before it comes into contact with organisms that may be harmed.

FDA addresses primary receptor issues, such as a child assisting in animal care or living in proximity to family farm animals, as public health issues under the act rather than through NEPA evaluation. See the response to comment 22, above.

45. Proposed § 25.33(d)(5) states that an action on a marketing application or supplement for an animal drug intended for therapeutic use under a prescription or veterinary order is categorically excluded and, therefore, ordinarily does not require an EA or an EIS. One comment contended that prescription animal drugs that are categorically excluded under proposed § 25.33(d)(5) could subsequently require an EA if they become available OTC. The comment assumes this is an unintended result and that grandfathering would be appropriate. The comment recommended that proposed § 25.33(d)(5) be revised to include a statement indicating that an animal drug that was once categorically excluded should not subsequently require an EA if it becomes available OTC.

The comment is correct in its assertion that a categorically excluded prescription animal drug could require an EA when the agency acts on an application to switch the drug to OTC availability. However, the comment incorrectly concludes that such a result is anomalous and unintended. As discussed in the preamble to the proposal (61 FR 14922 at 14932, 61 FR 19476 at 19486), the therapeutic use of an animal drug under a prescription by a veterinarian results in the drug being

administered to a limited number of animals for a limited amount of time. The agency's experience in reviewing EA's for these types of veterinary products indicates that this limited use results in no significant environmental impact. The limitations inherent in prescription use are not found in OTC use. Broader use and greater introduction of the drug into the environment may occur with OTC availability. Therefore, the agency believes that prescription to OTC switches of animal drugs warrant consideration through an EA. Grandfathering is not appropriate.

46. One comment stressed the importance of interpreting the term ''therapeutic use'' as it is used in the categorical exclusion for prescription veterinary drugs in proposed § 25.33(d)(5) independent of the percentage of the herd treated. The comment indicated that if prescription use were limited to single animal treatment, the section would cease to be an important measure to reduce the number of EA's.

Prescription animal drugs, by definition under the act, are limited to use under the professional supervision of a licensed veterinarian and, thus, are expected to be administered to a limited number of animals for a limited amount of time. Specifically, products intended for use by prescription require a veterinarian diagnosis of the disease or condition to be treated. The nature of this process limits the use of the prescription product and its introduction into the environment. Further, administration of the drug product by a veterinarian affords an added level of control over the use and disposal of the drug product. All veterinarians are trained on appropriate drug use procedures. Therefore, allowing a categorical exclusion under these circumstances is appropriate and the agency does not intend to interpret therapeutic use, as it pertains to proposed § 25.33(d)(5), based on the number or percentage of animals treated.

It is important to note that the agency's decision to propose this categorical exclusion of prescription animal drug products is primarily based upon its experience in reviewing EA's for these products. The EA's that comprise the bulk of agency experience in this area are for products used in terrestrial species. The agency has limited experience with reviewing drugs that will be used for the treatment of diseases in fish and other aquatic species. For this reason, the agency is revising proposed § 25.33(d)(5) to clarify that it applies only to terrestrial species. The section has been revised to state, ''Drugs intended for use under prescription or veterinarian's order for therapeutic use in terrestrial species.''

47. One comment noted that the same experience that led the agency to categorically exclude prescription animal drugs under § 25.33(d)(5) could ultimately result in all animal drug products being excluded regardless of whether they are prescription or over the counter (OTC), subject to extraordinary circumstances.

FDA will not speculate on future categorical exclusions. The agency based its decision to categorically exclude prescription animal drugs intended for therapeutic use on its extensive experience in reviewing EA's for those products. As the agency gains experience in reviewing other classes of drug products, additional categorical exclusions may be proposed. In all instances, FDA will require an EA to be prepared for products that would ordinarily be categorically excluded if there are extraordinary circumstances, see § 25.21.

48. Proposed § 25.33(h) would categorically exclude the withdrawal of approval of a food additive petition that reduces or eliminates animal feed uses of a food additive. One comment questioned whether the disposal of nonnutritive oil in animal feed requires a food additive petition.

The inclusion of nonnutritive oils in animal feeds requires the submission of a food additive petition and the preparation of an EA. (See the response to comment 35, above.) The categorical exclusion for the withdrawal of approval of a food additive petition has no bearing on whether a food additive petition, and corresponding EA for the petition, would be required for the nonnutritive oil.

D. Subpart D—Preparation of Environmental Documents

49. Proposed part 25 regulations focus on the use and disposal from use of FDA-regulated articles, and do not routinely require submission of information regarding manufacturing sites or a certification of compliance with Federal, State, and local emission requirements. One comment recommended that manufacturing and production considerations continue to be included in the environmental evaluation process and suggested that FDA consider potential occupational exposures and worker safety. The comment also expressed concern that by basing some categorical exclusions, specifically § 25.31(b), on presumed toxicity of a substance disposed of after use, the agency ''ignores the very substantial environmental impacts that may arise from manufacture'' of the product.

Another comment by the same author expressed particular concern about secondary and tertiary manufacturing processes involving food additives that may result in uncontrolled end products. The comment cited as an example a nonnutritive food grade oil that may be synthesized by a primary producer who then sells it to a secondary manufacturer for ingredient use in food product processing. The comment recommended that production of food additives, color additives, and GRAS substances not be included as a categorical exclusion and that the environmental impact of secondary or tertiary manufacturing be considered in an EA. Several related comments recommended that the production, processing, and disposal of nonnutritive oils, including the impact of liquid and solid oil components, the effect of processing on the form of the food additive entering the environment, and the potential nutritional impact of nonnutritive oils on microorganisms and invertebrates be included in EA's.

The agency has determined that its environmental evaluation process need not generally include a review of information on the manufacturing and production of FDA-regulated products, including food additives, color additives, and GRAS substances. This determination forms part of the basis for FDA's establishment of additional categorical exclusions for certain actions that currently require consideration of production sites in EA's and is the basis for FDA's decision that, for those actions requiring an EA, the EA will generally focus on potential impacts resulting from product use and disposal. Federal, State, and local environmental protection agencies are responsible for issuing regulations, permitting and licensing facilities, and enforcing compliance with those requirements that are necessary to ensure adequate protection of the environment from emissions resulting from production operations. Emergency response training and worker safety/training are under the purview of these agencies and/or the Occupational Safety and Health Administration (OSHA).

As discussed in the preamble to the proposed rule (61 FR 14922 at 14933, 61 FR 19476 at 19487), after reviewing hundreds of EA's that contained information regarding manufacturing sites, the agency found that FDA-regulated articles produced in compliance with applicable emission and occupational safety requirements will not significantly affect the

environment. However, if information available to the agency or the applicant establishes that a general or specific emission requirement issued by Federal, State, or local environmental agencies does not adequately address unique emission circumstances, and the emission may harm the environment, there would be sufficient grounds for FDA to request manufacturing information in an EA. Likewise, in accordance with CEQ regulations (40 CFR 1508.27(b)(10)), any action that threatens to violate a Federal, State, or local law or other requirement imposed for the protection of the environment would fall under § 25.21 (Extraordinary circumstances), and an EA would be required for the proposed action. Thus, although manufacturing site information will not routinely be requested, there may be specific circumstances that would require the submission of such information.

Concerning the comment about secondary and tertiary food additive production sites, FDA usually considers these facilities to be sites of use. The agency has found, with certain exceptions, that environmental introductions of food additives, color additives, and GRAS substances at secondary and tertiary production sites are minimal because these substances are typically meant to be incorporated into and function in food, food packaging, or food-contact equipment. Secondary direct food additives and nonfunctional components of food-packaging materials may, however, enter the environment at use sites because these additives are used as processing aids in the production of food and food-packaging materials, and are not intended to be present in the food or the finished packaging material. The agency did not propose a new categorical exclusion specifically for secondary direct additives, therefore, actions on these types of additives will generally require an EA. However, the agency notes that actions on certain secondary direct additives may qualify for exclusion under § 25.32 (j), (q), or (r), as revised, because they are used as components of the food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use, are pesticides registered by EPA under FIFRA and subject to FDA's regulatory authority as food additives for the same use, or are substances that occur naturally in the environment. As discussed above in response to comment 33, the agency will continue to require EA's for certain actions involving nonfunctional components of food-packaging materials. The agency will also require EA's for any normally excluded action if there are extraordinary circumstances suggesting that the action may have significant effects at use sites.

Regarding the example in the comment of a nonnutritive food oil, these actions do not qualify for exclusion under § 25.32(k), as revised, and require an EA because actions on these types of substances have the potential for significant environmental effects (see the responses to comments 35 and 48, above). The EA will take into consideration the potential effects raised in the comment, including introductions at all use and disposal sites (see, for example, the EA and FONSI for FDA's action on the fat substitute olestra (Docket No. 87F0179)).

50. Several comments suggested revisions to proposed § 25.40(a), which states: ''The EA shall focus on relevant environmental issues and shall be a concise, objective, and well-balanced document that allows the public to understand the agency's decision.'' Two comments recommended the inclusion of a statement that the focus of the environmental review would be on the use and disposal of FDA-regulated articles, but not the manufacturing. One comment recommended substituting the following sentence: ''The EA shall focus on relevant environmental issues relating to the use and disposal from use of FDA regulated articles and shall be a concise, objective, and well balanced document,'' thus eliminating the phrase that the EA shall be ''a document that allows the public to understand the agency's decision.'' One comment requested additional language stating that manufacturing site information, including emission information, would not be required.

The EA formats in current part 25, which have been eliminated in the proposed rule, focus on an analysis of the use and disposal of FDA-regulated articles. To clarify the focus of EA's under the proposed regulations, FDA agrees with the suggestion to amend proposed § 25.40(a) to state that ''The EA shall focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles * * * *'' Inclusion in the final regulation of a statement to the effect that emission information from production sites is not required in EA's would be contrary to FDA's position, as stated in the preamble to the proposed rule (61 FR 14922 at 14934, 61 FR 19476 at 19487 and 19488), that when information establishes that emission requirements promulgated by Federal, State, or local environmental protection agencies do not address unique emission circumstances and the emissions may harm the environment, FDA will request manufacturing information in an EA.

The phrase included in the proposed regulations that an EA should be ''a document that allows the public to understand the agency's decision'' is consistent with CEQ environmental policies and objectives and will not be deleted. NEPA procedures must ensure that environmental information is available to public officials and citizens (40 CFR 1500.1(b)). Thus, among other things, environmental documents need to be written in plain language so that the public can readily understand them (see, e.g., § 1502.8).

51. Proposed § 25.40(a) states that EA's shall include a brief discussion of alternatives to the proposed action as described by section 102(2)(E) of NEPA. Proposed § 25.40(a) also states that if potentially adverse impacts on the environment are identified in the EA, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. One comment stated that this requirement ''would only require applicants or petitioners to discuss 'reasonable' alternatives where 'potentially adverse environmental impacts are identified,' '' and, therefore, is inconsistent with 40 CFR 1508.9.

FDA does not believe there is an inconsistency between proposed §§ 25.40(a) and 1508.9. EA's are to be concise public documents to determine whether a more detailed analysis, an EIS, is required (§ 1508.9). A discussion of alternatives other than those which are ''reasonable'' is inconsistent with this overriding principle. Therefore, FDA is not amending § 25.40(a) in response to this comment.

52. One comment requested that proposed § 25.40(a) include a maximum page limit for EA documents.

Because the number or pages for any EA will vary in relation to the complexity of relevant environmental issues, and such flexibility should be permitted by the regulations, FDA declines to include in its regulation a page limit for EA's. CEQ regulations do not specify any limit on the number of pages in EA's. FDA suggested in the preamble (61 FR 14922 at 14934, 61 FR 19476 at 19488) that, as a general rule, an EA should normally be no more than 30 pages, not including test reports and data.

53. The last sentence of proposed § 25.40(a) allows for a tiered environmental testing scheme that would result in test termination when

sufficient data are available to suggest that no significant environmental impact will occur as a result of the potential agency action. One comment suggested that this sentence be changed to state that when results of the initial tier of testing indicate that testing may be stopped, the EA need only contain a certification which states that a PEC/PNEC calculation has been completed and the ratio of the PEC to PNEC is less than one.

The agency declines to include the suggested revision. Proposed § 25.40(a) describes general EA requirements for all FDA-regulated articles. While a tiered testing approach may be adopted by applicants and petitioners of all products regulated by the agency, the language recommended in the comment is limited to human drugs, biologics, and animal drugs. Thus, the inclusion of the suggested language in § 25.40(a) is not appropriate. Additionally, as discussed earlier in response to comment 26, if a PEC/PNEC ratio is used, FDA would need to review the underlying data that supports the PEC/PNEC ratio.

54. FDA has proposed to remove the EA and abbreviated EA formats and any reference to the formats currently found in § 25.31a and to provide appropriate formats in guidance documents. One comment emphasized that to the extent such guidance documents amend or revise informational requirements under NEPA, such requirements are impermissible unless the guidance documents are issued through notice and comment rulemaking under the Administrative Procedure Act (the APA) (5 U.S.C. 553), and the agency consults with CEQ to ensure that the FDA guidance is consistent with NEPA and CEQ requirements.

The APA (5 U.S.C. 553) does not require notice of interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice except when notice is required by other statute. Guidance documents are issued by FDA to provide assistance to the regulated industry and interested parties by interpreting and clarifying requirements that have been imposed by statute or regulation. They reflect the agency's current thinking on the implementation of its regulatory scheme, and because they are not binding on industry or on the agency, they do not create requirements. Consequently, guidance documents are not subject to the notice and comment rulemaking provisions of the APA.

CEQ regulations (40 CFR 1507.3) encourage agencies to publish explanatory guidance for their own procedures and to revise them as necessary to ensure full compliance with the purposes and provisions of NEPA. Use of guidances provides the agency with greater flexibility to interpret requirements under its NEPA procedures in a manner that responds to the evolving nature of environmental science and the needs of industry and interested parties. In the **Federal Register** of February 27, 1997, FDA announced its adoption of GGP's, which describes the agency's policies and procedures for the development, issuance, and use of guidance documents, including public input in the development of guidance and publication of a notice of availability. Any further development of guidance related to FDA's implementation of NEPA will be developed in accordance with these GGP's. Thus, although guidance documents that clarify the submission of environmental information to FDA are not required to undergo the notice and comment rulemaking procedures of the APA, such guidance documents are subject to public comment and input under the agency's GGP's. Until guidance documents are issued in accordance with the GGP's, applicants that need to submit an EA may follow the EA formats previously published by the agency or may contact the appropriate center for specific guidance on preparing the EA.

In the **Federal Register** of January 11, 1996 (61 FR 1031), FDA announced the availability of a guidance document entitled, ''Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements.'' That guidance was intended to assist industry by providing guidance on how to prepare EA's for submission to CDER under current part 25 as part of NDA's, antibiotic applications, abbreviated applications, and IND's. In preparing the ''Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements,'' CDER consulted with CEQ and gave CEQ an opportunity to review and comment on the guidance prior to its issuance. This guidance will be revised, as necessary, to ensure that the guidance is consistent with this final rule when it becomes effective. The agency intends to continue its working relationship with the CEQ in issuing additional guidance documents under the final rule.

55. Two comments requested that a general format for EA's be incorporated into proposed § 25.40(a). Both comments expressed concern that removal of the general format from part 25 may invite regulatory expansion, i.e., the opportunity for FDA to request more information.

As explained above and in the preamble to the proposal (61 FR 14922 at 14933, 61 FR 19476 at 19487), the agency, in consultation with CEQ, has decided that to the extent that EA formats are helpful, they are more appropriately placed in guidance documents. The formats included in former part 25 were developed to be applicable to all FDA-regulated articles. Due to the diverse nature of the products regulated by FDA, not all format items were relevant to each action. Consequently, some EA's contained unnecessary information and, in some instances, information needed to assess the environmental effects of an action was not initially submitted to the agency. Thus, the formats may be more appropriately included in guidance documents prepared by each center. Guidance documents will allow FDA to suggest EA formats that focus on important environmental issues relating to each type of product regulated by FDA and will assist the preparer in tailoring individual EA's to focus on environmental issues specific to the particular action.

56. Current § 25.31a establishes EA formats for proposed actions to approve food or color additives, drugs, biological products, animal drugs, and some medical devices, to affirm food substances as GRAS, and to grant requests for exemption from regulation as a food additive. One comment noted that in the prescribed EA format, an applicant or petitioner is required to identify the natural resources needed to produce, transport, use and/or dispose of a given amount of any product which is the subject of the action; to describe measures taken to avoid or mitigate potential adverse environmental impacts associated with the proposed action; and to describe in detail the environmental impact of all reasonable alternatives to the proposed action, including those that will enhance the quality of the environment and avoid some or all of the adverse environmental impacts of the proposed action (§ 25.31a(a)). The comment expressed concern that the proposed rule ''completely eliminates'' those obligations as they apply to marketing applications for paclitaxel derived from the Pacific yew.

Proposed § 25.21 will require an EA for any action, including one involving natural resources, that is ordinarily excluded if the action may have a significant effect on the environment. Proposed § 25.40(a) establishes that an EA shall include a brief discussion of the need for the proposed action,

alternatives to it, and environmental impacts of the proposed action and alternatives. If potentially adverse impacts on the environment are identified in the EA, the EA shall also discuss any alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The agency has determined that more specific information regarding the nature and scope of information that should be included in an EA will be provided in guidance documents rather than through regulatory requirements. Use of guidance documents will provide the agency with greater flexibility to implement NEPA in a manner that responds to the evolving nature of environmental science and the needs of industry and other interested parties. See the response to comment 54, above. As a result of this decision, topics to be analyzed in each EA will be discussed and clarified in guidance documents that will be issued by the center responsible for the underlying action. Such topics will include the use of natural resources in the proposed action (if relevant), and a description of measures that have been taken to avoid or mitigate adverse environmental impacts that may result from the proposed action.

With regard to marketing applications for drugs involving paclitaxel derived from the Pacific yew, FDA published a notice in the **Federal Register** (61 FR 58694), explaining the extent of environmental documentation that needs to be submitted to the agency for drug products containing paclitaxel. See the response to comment 15, above. Persons interested in the agency's application of NEPA requirements with regard to paclitaxel and the Pacific yew are encouraged to review that notice.

57. Proposed § 25.40(d) states that EA's may incorporate by reference information presented in other documents that are available to FDA and to the public. One comment recommended that this section be revised to clarify that other EA's for approved FDA-regulated articles may be incorporated by reference into an EA.

EA's that are available under the Freedom of Information Act are public information and therefore may be incorporated by reference into an EA to the extent that they are relevant to the action addressed in the EA. Information that is not publicly available but to which an applicant or petitioner has a right of reference or ownership may also be incorporated by that applicant or petitioner into an EA. In accordance with proposed § 25.51(a), however, such confidential information shall be summarized in the EA to the extent possible. The agency does not find it necessary to revise the proposed regulation to further clarify this point.

58. Proposed § 25.40(e) states that the agency evaluates the information contained in an EA, along with any public input, to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether the agency should prepare a FONSI or EIS. One comment requested that this section be revised to define and restrict specific procedures in manufacturing and disposal to effectively prevent opportunities for some types of environmental release.

Defining and restricting specific procedures in manufacturing and disposal to prevent pollution are more appropriately handled by Federal, State, or local environmental protection agencies that have regulatory authority and more expertise in those matters. However, as part of FDA's NEPA review process, alternatives and mitigation measures are considered by FDA.

59. Proposed § 25.43 states that in cases where EIS's are required, the agency will prepare, at the time of its decision, a concise public record of decision. One comment asserted that this section should explicitly address the CEQ provisions governing limitations on actions during the NEPA process. CEQ regulations (40 CFR 1506.1(b)) require an agency to take appropriate action to ensure that the objectives and procedures of NEPA are achieved if the agency is aware that an applicant is about to take an action within the jurisdiction of the agency that will have adverse environmental impacts or will limit the choice of reasonable alternatives.

FDA is not required under 40 CFR 1507.3(b), and does not see any need, to explicitly include in its procedures specific language to implement 40 CFR 1506.1(b). Because an agency's procedures must supplement CEQ regulations, all CEQ regulations in 40 CFR parts 1500 through 1508 are incorporated by reference into FDA's policies and procedures implementing NEPA.

60. Proposed § 25.45 (Responsible agency official) states that the agency official identified in part 5 as being responsible for the underlying application or petition is responsible for preparing environmental documents. One comment suggested that § 25.45 be revised to require the responsible agency official to be available to review any questions arising from the preparation of an EA. Two comments recommended that part 5 be amended to include a provision that establishes the Center Directors as the responsible officials for deciding the existence of extraordinary circumstances under proposed § 25.21 and prohibits redelegation of such authority. One of these comments also requested revisions to make it clear that any decision by the Center Director on the question of extraordinary circumstances constitutes final agency action.

FDA does not find it necessary to revise proposed § 25.45 to require the responsible agency official to be available to review questions arising from the preparation of an EA. The FDA official responsible for preparing environmental documents is available to review questions concerning environmental issues and to meet with interested parties (see, e.g., § 10.65 (21 CFR 10.65)). In proposed § 25.40, FDA specifically encourages interaction between the responsible agency official and those submitting EA's during the preparation of the environmental documents.

FDA also declines to amend part 5. Part 5 delegates to specific agency officials responsibility for taking particular actions on behalf of the agency. Responsibility for actions on petitions and applications is generally delegated to the Director or Deputy Director(s) of the center responsible for reviewing submissions relating to the FDA-regulated product for which an action is requested. Consistent with CEQ's policy that the disciplines of those who prepare environmental documents be appropriate to the scope and issues of the document, see e.g., 40 CFR 1502.6, the Center Directors delegate responsibility (e.g., authority to determine extraordinary circumstances and to mediate conflicts between reviewers and sponsors) to individuals within their organization who have specialized training and expertise to evaluate all relevant issues. Individuals in each center who have training and experience in environmental science and in implementing environmental statutes are responsible for determining the adequacy of EA's and claims for categorical exclusion and the existence of extraordinary circumstances. These individuals are expected to consult with their supervisors and other management officials as needed. Specific delegations of responsibility are available to the public through each center office.

Furthermore, each center has appeals procedures by which decisions of center personnel can be appealed to the Center Director. The Center Director's decision does not necessarily, however, constitute final agency action. A procedure for internal review of agency

decisions is established in § 10.75(a) (21 CFR 10.75(a)), which states that a decision of any FDA employee, other than the Commissioner, is subject to review by the employee's supervisor. Thus, the proposal that a Center Director's decision necessarily constitutes final agency action is contrary to FDA regulations and FDA does not believe that its regulations should be modified.

E. Subpart E—Public Participation and Notification of Environmental Documents

61. Proposed § 25.50(b) states that many actions performed by FDA are protected from disclosure by the act, the Trade Secret Act (the TSA) (18 U.S.C. 1905), and FDA regulations and ''unless the existence of an application for human drugs * * * has been made publicly available, the release of the environmental document before approval of human drugs * * * is inconsistent with statutory requirements imposed on FDA.'' One comment stated that this provision conflicts with the requirements of NEPA and CEQ that mandate public involvement at the earliest possible time. The comment stated that FDA may not completely abandon NEPA's public participation provisions by broadly invoking protection under the TSA. The comment stated that at least for NDA's and ANDA's, FDA clearly has authority to release environmental documents following issuance of an approvable letter to the applicant. The comment cited two Federal court cases, *Flint Ridge Development Co.* v. *Scenic Rivers Association of Oklahoma et al.*, 426 U.S. 776 (1976) and *Concerned About Trident* v. *Rumsfeld*, 555 F.2d 817 (D.C. Cir. 1977), to support the proposition that exceptions to NEPA's requirements have been construed narrowly.

Proposed § 25.50(b) is consistent with NEPA and CEQ regulations. Section 102 of NEPA (42 U.S.C. 4332)

> (D)irects that, to the fullest extent possible: (1) The policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in [NEPA], and (2) all agencies of the Federal government shall— * * * (C) include in every recommendation * * * for * * * major Federal action significantly affecting the quality of the human environment, a detailed statement by the responsible official on—(i) the environmental impact of the proposed action (emphasis added).

Section 102 of NEPA further requires copies of any such detailed statement and the comments and views of the appropriate Federal, State, and local agencies, which are authorized to develop and enforce environmental standards, to be made available to the President, CEQ, and to the public as provided in 5 U.S.C. 552. CEQ regulations (40 CFR 1500.6) state that ''the phrase 'to the fullest extent possible' in section 102 means that each agency of the Federal Government shall comply with that section unless existing law applicable to the agency's operations expressly prohibits or makes compliance impossible.''

The TSA expressly prohibits any officer or employee of the United States from publishing, divulging, disclosing, or making known in any manner or to any extent not authorized by law any information which concerns or relates to trade secrets, processes, operations, styles of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association. The TSA covers trade secrets as well as confidential commercial or financial information. Therefore, FDA is prohibited from disclosing trade secrets and confidential commercial information except to the extent authorized by law.

Under section 301(j) of the act (21 U.S.C. 331(j)), FDA is authorized to disclose trade secret information only to the Secretary of the Department of Health and Human Services or officers or employees of the Department, courts when relevant in any judicial proceeding under the act, either House of Congress, or, to the extent of matter within its jurisdiction, any committee or its subcommittee or any joint committee of Congress or its subcommittee. FDA is not authorized to disclose trade secrets to any other parties.

The comment cited two cases. *Flint Ridge* stands for the proposition that the only time that a Federal agency can avoid compliance with NEPA under the ''to the fullest extent possible'' caveat is when a clear and unavoidable conflict in statutory authority exists, in which case NEPA must give way. In Concerned about Trident, the Court rejected the Department of Defense-Navy's attempt to exempt from the mandate of NEPA strategic military decisions made by the Department of Defense-Navy because the Navy pointed to no existing specific statutory authority prohibiting compliance with NEPA in that case or making such compliance impossible.

Proposed § 25.50(b) is consistent with NEPA's direction to implement its policies ''to the fullest extent possible,'' as the case law has interpreted that phrase. In those instances in which the TSA and section 301(j) of the act prohibit FDA from disclosing environmental information to the public, compliance with NEPA is impossible and NEPA must give way. FDA cannot disclose to the public environmental information prior to taking action to approve certain marketing applications. Thus, FDA does not contravene NEPA when it refuses to disclose information in such circumstances.

Furthermore, FDA's procedures comply with NEPA's requirements to implement NEPA to the fullest extent possible because the procedures require FDA to review and/or prepare environmental documentation for any major Federal action before taking the action unless the action meets criteria for categorical exclusion. Moreover, FDA's procedures specifically provide that information will be released to the public in accordance with NEPA when, and to the extent, permitted by the TSA and other laws governing FDA's operations. Clearly, FDA is not completely abandoning NEPA's public participation provisions. If FDA is not prohibited under the TSA and the act from disclosing specific environmental information before FDA takes action, FDA will disclose that environmental information at the earliest possible time before action is taken. To the extent that compliance with the TSA and the act make impossible disclosure of environmental information before action is taken, FDA will disclose environmental information after the action is taken to the extent permitted under the TSA and the act.

Finally, § 25.50 is also consistent with the requirement that environmental information be made available to the public as provided in the Freedom of Information Act (the FOIA) (5 U.S.C. 552). Although the FOIA requires an agency to make available to the public most information available to the agency, certain matters are exempt from disclosure. Specifically, the FOIA exempts from disclosure trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

62. Proposed § 25.52(a) states that if an EIS is prepared for a drug, animal drug, biologic product, or device, it will become available to the public only at the time of the approval of the product. One comment asserted that this provision ''cuts back significantly on one of the most fundamental requirements of NEPA and the CEQ regulations—the ability of the public to review and comment on proposed agency decisions.'' The comment stated that the proposal ''constitutes a complete repeal of the agency's current NEPA regulations providing for public

involvement in the EIS process and, as such, it must be rejected.''

The agency disagrees. Proposed § 25.52 does not repeal the agency's regulations providing for public involvement in the EIS process but merely clarifies that when there is a clear and unavoidable conflict between NEPA's public disclosure goals and other laws governing FDA's disclosure of information, FDA must follow the disclosure laws that govern its operations. As discussed in response 61 above, the agency is limited in its ability to disclose to the public information contained within certain marketing applications. The agency will generally make an EIS available to the public at the time of approval of the relevant drug, animal drug, biological product, or device (§ 25.52(a)) but, in instances where disclosure of an application has occurred, the agency will abide by its responsibility to make a diligent effort to involve the public while concurrently complying with its own disclosure requirements (§ 25.52(c)).

F. Subpart F—Other Requirements

63. Section 25.60 states that in accordance with Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions,'' January 4, 1979, FDA will consider the environmental effects abroad of its potential actions. One comment claimed that under this provision, Executive Order 12114, not NEPA, would govern environmental impacts that may occur abroad as a result of FDA action. The comment stated that as a result, FDA's proposal would not govern environmental impacts associated with harvest of Pacific yew trees in Canada for paclitaxel marketed in the United States. The comment cited *Environmental Defense Fund* v. *Massey*, 986 F.2d 528 (D.C. Cir. 1993), stating that the Court of Appeals for the D.C. Circuit rejected the notion that NEPA only governs activities within the United States.

Executive Order 12114 and proposed § 25.60 (current § 25.50) have not changed since 1985. Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions,'' represents the U.S. Government's ''exclusive and complete determination of * * * actions to be taken by Federal agencies to further the purpose of the National Environmental Policy Act with respect to the environment outside the United States, its territories, and possessions.'' The agency issued current § 25.50 to implement this executive order. FDA requirements include the consideration of potential environmental effects of an action on a foreign nation, current § 25.50(a)(2) (proposed § 25.60(a)(2)). In the event the agency action would have a significant environmental effect on the foreign nation, the agency official will require additional environmental documentation, current § 25.50(c) (proposed § 25.60(c)).

In the case cited in the comment, *Environmental Defense Fund* v. *Massey*, 986 F.2d 528, 532 (D.C. Cir. 1993), the court held that the National Science Foundation must comply with NEPA before going forward with plans to incinerate food waste in Antarctica. The court expressly limited its decision to the unique circumstances of Antarctica, stating, ''we do not decide today how NEPA might apply to actions in a case involving an actual sovereign.'' (Massey, at 537.) The court did not rule on the applicability of Executive Order 12114.

The comment's allegation that FDA's proposal would not govern the environmental impacts associated with the harvest of the Pacific yew in Canada for paclitaxel marketed in the United States is without basis. FDA is required to consider the environmental impacts of its actions either under NEPA or the Executive Order. Executive Order 12114 states if the responsible official determines that an action may have a significant environmental effect abroad, the responsible official shall prepare appropriate environmental documents. Additionally, as discussed in the response to comment 15, above, FDA issued a notice in the November 18, 1996, **Federal Register** explaining the environmental information to be submitted with marketing applications for drug products containing paclitaxel.

III. Conforming Amendments

The environmental regulations in part 25 are cited throughout FDA's regulations. Because FDA is revising part 25, the agency is taking this opportunity to make conforming amendments to 21 CFR parts 10, 20, 71, 101,170, 171, 312, 314, 315, 511, 514, 570, 571, 601, 812, 813, and 814 to reflect revised part 25. These conforming amendments will ensure the accuracy and consistency of the regulations.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities unless the rule is not expected to have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act (Pub. L. 104–4) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation). The following analysis demonstrates that this final rule is consistent with the principles set forth in the Executive Order and in these two statutes. The final rule is a significant but not an economically significant regulatory action under Executive Order 12866 and the rule does not impose any mandates on State, local, or tribal governments, or the private sector, that will result in an annual expenditure of $100,000,000 or more.

Based on the approximate number of EA's that FDA currently receives each year and the resources needed to prepare them, the agency estimates that the reduced requirements for submitting EA's will result in an annual cost savings to industry of approximately $15.7 million. Two letters received by FDA in response to the proposed rule commented that the rule would eliminate a majority of EA's that the respondents, or their members, have been required to submit in the past. These comments are consistent with the estimate presented here. The basis for this estimate is as follows:

Human Pharmaceuticals

Approximately 125 EA's related to human pharmaceuticals will be eliminated annually under the final rule. About one-half of these are abbreviated EA's; the remainder are full assessments. Based on industry estimates, FDA assumes that the average cost of preparing an abbreviated assessment was approximately $40,000, while the average cost of a full assessment was approximately $200,000. These assumptions yield a cost savings of about $2.5 million for abbreviated EA's and $12.5 million for full EA's, for a total savings to industry from the reduced requirements of EA's relating to human pharmaceuticals of approximately $15 million per year.

Veterinary Products

The changes eliminate approximately 37 abbreviated EA's for veterinary products each year, at an industry-estimated average cost of approximately $5,000 each. About 77 brief submissions, which currently require categorical exclusion criteria review, are also eliminated; these cost an industry-estimated $300 each to prepare. Total cost savings to the veterinary products industry under the proposal are thus approximately $208,000 per year.

Food Products

About 39 EA's per year received by the Center for Food Safety and Applied Nutrition (CFSAN) will be eliminated under the final rule. Approximately 30 of these would have been abbreviated EA's and 9 would have been full assessments under current rules. Based on industry estimates, FDA projects that the cost of producing most abbreviated EA's for CFSAN is approximately $2,500 and the average cost of producing a full EA is approximately $50,000. These assumptions imply an annual cost savings of approximately $75,000 for abbreviated EA's and $450,000 for full EA's, for a total annual savings to the foods industry of approximately $525,000.

In addition to these savings to industry, the final rule will improve FDA efficiency by eliminating agency review costs of approximately $1 million per year.

As these regulations will not impose significant new costs on any firms, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commissioner certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: National Environmental Policy Act; Reporting Provisions.

Description: FDA has previously issued regulations that implement NEPA (part 25). This final rule calls for applicants and petitioners to submit environmental information to FDA, in the form of EIS's, EA's, or claims for categorical exclusion, where appropriate. NEPA requires such reporting to enable FDA to take into account in its decisionmaking process the potential impact of agency actions on the environment.

This final rule will reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EIS nor an EA is required. FDA is also amending these regulations to ensure that the NEPA procedures are more concise and understandable to the public, and to reflect current FDA policy with respect to environmental considerations.

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the appropriate contact person listed at the beginning of this document.

Description of Respondents: Persons and businesses, including small businesses.

ESTIMATED ANNUAL REPORTING BURDEN

CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per Responses	Total hours
25.15(a), (d)	455	11.82	5,376	7.94	42,685
25.40(a), (c)	455	.13	58	2832.93	164,310
Total					206,995

This estimate represents the total reporting burden for the amended regulations. The total reporting burden for the regulations in part 25 before the amendments was 710,987 hours; thus, the amended regulations will result in an estimated net decrease in burden of 503,992 hours, a reduction of more than 70 percent.

The information collection provisions in this final rule have been approved under OMB Control No. 0910–0332. This approval expires June 30, 1999. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

21 CFR Part 71

Administrative practice and procedure, Color additives, Confidential business information, Cosmetics, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171

Administrative practice and procedure, Food additives.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business

information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 511

Animal drugs, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 570

Animal feeds, Animal foods, Food additives.

21 CFR Part 571

Administrative practice and procedure, Animal feeds, Animal foods, Food additives.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 10, 20, 25, 71, 101, 170, 171, 312, 314, 511, 514, 570, 571, 601, 812, and 814 are amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

2. Section 10.30 is amended in paragraph (b) by revising item C to read as follows:

§ 10.30 Citizen petition.

* * * * *

(b) * * *

C. Environmental impact.

(A) claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

* * * * *

3. Section 10.40 is amended by revising paragraph (b)(1)(ix) to read as follows:

§ 10.40 Promulgation of regulations for the efficient enforcement of the law.

* * * * *

(b) * * *

(1) * * *

(ix) a reference to the existence or lack of need for an environmental impact statement under § 25.52 of this chapter; and

* * * * *

PART 20—PUBLIC INFORMATION

4. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 190; 19 U.S.C. 2531–2582; 21 U.S.C. 1401–1403.

5. Section 20.100 is amended by revising paragraph (c)(3) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(3) Environmental assessments; finding of no significant impact, in § 25.51 of this chapter, or draft and final environmental impact statements, in § 25.52 of this chapter.

6. Part 25 is revised to read as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

Subpart A—General Provisions

Sec.

Subpart B—Agency Actions Requiring Environmental Consideration

Subpart C—Categorical Exclusions

Subpart D—Preparation of Environmental Documents

Subpart E—Public Participation and Notification of Environmental Documents

Subpart F—Other Requirements

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 351, 354–361 of the Public Health Service Act (42 U.S.C. 262, 263b–264); 42 U.S.C. 4321, 4331–4335; 40 CFR parts 1500–1508; E.O. 11514, 3 CFR 1966–1970, Comp., p. 902, as amended by E.O. 11991, 3 CFR 1977 Comp., p. 123. E.O. 12114, 3 CFR 1977 Comp., p. 123.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

Subpart A—General Provisions

§ 25.1 Purpose.

The National Environmental Policy Act of 1969 (NEPA), as amended, directs that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA. All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements. The regulations in this part implement section 102(2) of NEPA in a manner that is consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. This part also supplements the regulations for implementing the procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in 40 CFR parts 1500 through 1508 and the procedures included in the ''HHS General Administration Manual, part 30: Environmental Protection'' (45 FR 76519 to 76534, November 19, 1980).

§ 25.5 Terminology.

(a) Definitions that apply to the terms used in this part are set forth in the CEQ regulations under 40 CFR part 1508. The terms and the sections of 40 CFR part 1508 in which they are defined follow:

(1) Categorical exclusion (40 CFR 1508.4).
(2) Cooperating agency (40 CFR 1508.5).
(3) Cumulative impact (40 CFR 1508.7).
(4) Effects (40 CFR 1508.8).
(5) Environmental assessment (EA) (40 CFR 1508.9).
(6) Environmental document (40 CFR 1508.10).
(7) Environmental impact statement (EIS) (40 CFR 1508.11).
(8) Federal agency (40 CFR 1508.12).
(9) Finding of no significant impact (40 CFR 1508.13).
(10) Human environment (40 CFR 1508.14).
(11) Lead agency (40 CFR 1508.16).
(12) Legislation (40 CFR 1508.17).
(13) Major Federal action (40 CFR 1508.18).
(14) Mitigation (40 CFR 1508.20).
(15) NEPA process (40 CFR 1508.21).
(16) Notice of intent (40 CFR 1508.22).
(17) Proposal (40 CFR 1508.23).
(18) Scope (40 CFR 1508.25).
(19) Significantly (40 CFR 1508.27).

(b) The following terms are defined solely for the purpose of implementing the supplemental procedures provided by this part and are not necessarily applicable to any other statutory or regulatory requirements:

(1) *Abbreviated application* applies to an abbreviated new drug application, an abbreviated antibiotic application, and an abbreviated new animal drug application.

(2) *Active moiety* means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex chelate or clathrate) of the molecule responsible for the physiological or pharmacological action of the drug substance.

(3) *Agency* means the Food and Drug Administration (FDA).

(4) *Increased use* of a drug or biologic product may occur if the drug will be administered at higher dosage levels, for longer duration or for different indications than were previously in effect, or if the drug is a new molecular entity. The term ''use'' also encompasses disposal of FDA-regulated articles by consumers.

(5) *Responsible agency official* means the agency decisionmaker designated in part 5 of this chapter.

(c) The following acronyms are used in this part:

(1) CEQ—Council on Environmental Quality.
(2) CGMP—Current good manufacturing practice.
(3) EA—Environmental assessment.
(4) EIS—Environmental impact statement.
(5) The act—Federal Food, Drug, and Cosmetic Act.
(6) FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act.
(7) FONSI—Finding of no significant impact.
(8) GLP—Good laboratory practice.
(9) GRAS—Generally recognized as safe.
(10) HACCP—Hazard analysis critical control point.
(11) IDE—Investigational device exemption.
(12) IND—Investigational new drug application.
(13) INAD—Investigational new animal drug application.
(14) NADA—New animal drug application.
(15) NDA—New drug application.
(16) NEPA—National Environmental Policy Act of 1969.
(17) OTC—Over-the-counter.
(18) PDP—Product development protocol.
(19) PMA—Premarket approval application.

§ 25.10 Policies and NEPA planning.

(a) All FDA's policies and programs will be planned, developed, and implemented to achieve the policies declared by NEPA and required by CEQ's regulations to ensure responsible stewardship of the environment for present and future generations.

(b) Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time to ensure that planning and decisions reflect environmental values, to avoid delays later in the process, and to avoid potential conflicts.

(c) For actions initiated by the agency, the NEPA process will begin when the agency action under consideration is first identified. For actions initiated by applicants or petitioners, NEPA planning begins when FDA receives from an applicant or petitioner an EA or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions. FDA may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potential significant environmental effects.

(d) Environmental documents shall concentrate on timely and significant issues, not amass needless detail.

(e) If a proposed action for which an EIS will be prepared involves possible environmental effects that are required to be considered under statutes or Executive Orders other than those referred to under ''Authority'' in this part, these effects shall be considered in the NEPA review, consistent with 40 CFR 1502.25 and the HHS General Administration Manual, part 30: Environmental Protection.

Subpart B—Agency Actions Requiring Environmental Consideration

§ 25.15 General procedures.

(a) All applications or petitions requesting agency action require the submission of an EA or a claim of categorical exclusion. A claim of categorical exclusion shall include a statement of compliance with the categorical exclusion criteria and shall state that to the applicant's knowledge, no extraordinary circumstances exist. Failure to submit an adequate EA for an application or petition requesting action by the agency of a type specified in § 25.20, unless the agency can determine that the action qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34, is sufficient grounds for FDA to refuse to file or approve the application or petition. An EA adequate for filing is one that addresses the relevant environmental issues. An EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment.

(b) The responsible agency officials will evaluate the information contained in the EA to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS will be prepared. If significant effects requiring the preparation of an EIS are identified, FDA will prepare an EIS for the action in accordance with the procedures in subparts D and E of this part. If significant effects requiring the preparation of an EIS are not identified, resulting in a decision not to prepare an EIS, the responsible agency official will prepare a FONSI in accordance with § 25.41.

(c) Classes of actions that individually or cumulatively do not significantly affect the quality of the human environment ordinarily are excluded from the requirement to prepare an EA or an EIS. The classes of actions that qualify as categorical exclusions are set forth in §§ 25.30, 25.31, 25.32, 25.33, or 25.34.

(d) A person submitting an application or petition of a type subject to categorical exclusion under §§ 25.30,

25.31, 25.32, 25.33, or 25.34, or proposing to dispose of an article as provided in § 25.30(d) or 25.32(h), is not required to submit an EA if the person states that the action requested qualifies for a categorical exclusion, citing the particular categorical exclusion that is claimed, and states that to the applicant's knowledge, no extraordinary circumstances exist.

§ 25.16 Public health and safety emergencies.

There are certain regulatory actions that, because of their immediate importance to the public health or safety, may make full adherence to the procedural provisions of NEPA and CEQ's regulations impossible. For such actions, the responsible agency official shall consult with CEQ about alternative arrangements before the action is taken, or after the action is taken, if time does not permit prior consultation with CEQ.

§ 25.20 Actions requiring preparation of an environmental assessment.

Any proposed action of a type specified in this section ordinarily requires at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34:

(a) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved.

(b) Destruction or other disposition of articles condemned after seizure or whose distribution or use has been enjoined, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(c) Destruction or other disposition of articles following detention or recall at agency request, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(d) Disposition of FDA laboratory waste materials, unless categorically excluded in § 25.30(m).

(e) Intramural and extramural research supported in whole or in part through contracts, other agreements, or grants, unless categorically excluded in § 25.30 (e) or (f).

(f) Establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in §§ 25.30(k) or 25.31 (a), (b), (c), (h), (i), or (j), or 25.32 (a) or (p).

(g) Issuance, amendment, and enforcement of FDA regulations, or an exemption or variance from FDA regulations, unless categorically excluded in § 25.30 (h), (i), or (j), or § 25.32 (e), (g), (n), or (p).

(h) Withdrawal of existing approvals of FDA-approved articles, unless categorically excluded in §§ 25.31 (d) or (k), 25.32(m), or 25.33 (g) or (h).

(i) Approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, and granting of requests for exemption from regulation as a food additive, unless categorically excluded in § 25.32 (b), (c), (i), (j), (k), (l), (o), (q), or (r).

(j) Establishment of a tolerance for unavoidable poisonous or deleterious substances in food or in packaging materials to be used for food.

(k) Affirmation of a food substance as GRAS for humans or animals, on FDA's initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, unless categorically excluded in § 25.32 (f), (k), or (r).

(l) Approval of NDA's, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, and actions on IND's, unless categorically excluded in § 25.31 (a), (b), (c), (e), or (l).

(m) Approval of NADA's, abbreviated applications, supplements, and actions on INAD's, unless categorically excluded under § 25.33 (a), (c), (d), or (e).

(n) Approval of PMA's for medical devices, notices of completion of PDP's for medical devices, authorizations to commence clinical investigation under an approved PDP, or applications for an IDE, unless categorically excluded in § 25.34.

§ 25.21 Extraordinary circumstances.

As required under 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (see 40 CFR 1508.27 for examples of significant impacts). Examples of such extraordinary circumstances include:

(a) Actions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment; and

(b) Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law.

§ 25.22 Actions requiring the preparation of an environmental impact statement.

(a) There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS.

(b) EIS's are prepared for agency actions when evaluation of data or information in an EA or otherwise available to the agency leads to a finding by the responsible agency official that a proposed action may significantly affect the quality of the human environment.

Subpart C—Categorical Exclusions

§ 25.30 General.

The classes of actions listed in this section and §§ 25.31 through 25.34 are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Routine administrative and management activities, including inspections, and issuance of field compliance programs, program circulars, or field investigative assignments.

(b) Recommendation for an enforcement action to be initiated in a Federal court.

(c) Agency requests for initiation of recalls.

(d) Destruction or disposition of any FDA-regulated article condemned after seizure or the distribution or use of which has been enjoined or following detention or recall at agency request if the method of destruction or disposition of the article, including packaging material, is in compliance with all Federal, State, and local requirements.

(e) Extramural contracts, other agreements, or grants for statistical and epidemiological studies, surveys and inventories, literature searches, and report and manual preparation, or any other studies that will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment.

(f) Extramural contracts, other agreements, and grants for research for such purposes as to develop analytical methods or other test methodologies.

(g) Activities of voluntary Federal-State cooperative programs, including issuance of model regulations proposed for State adoption.

(h) Issuance, amendment, or revocation of procedural or administrative regulations and guidelines, including procedures for submission of applications for product development, testing and investigational use, and approval.

(i) Corrections and technical changes in regulations.

(j) Issuance of CGMP regulations, HACCP regulations, establishment standards, emergency permit control regulations, GLP regulations, and issuance or denial of permits, exemptions, variances, or stays under these regulations.

(k) Establishment or repeal by regulation of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.

(l) Routine maintenance and minor construction activities such as:

(1) Repair to or replacement of equipment or structural components (e.g., door, roof, or window) of facilities controlled by FDA;

(2) Lease extensions, renewals, or succeeding leases;

(3) Construction or lease construction of 10,000 square feet or less of occupiable space;

(4) Relocation of employees into existing owned or currently leased space;

(5) Acquisition of 20,000 square feet or less of occupiable space in a structure that was substantially completed before the issuance of solicitation for offers; and

(6) Acquisition of between 20,000 square feet and 40,000 square feet of occupiable space if it constitutes less than 40 percent of the occupiable space in a structure that was substantially completed before the solicitation for offers.

(m) Disposal of low-level radioactive waste materials (as defined in the Nuclear Regulatory Commission regulations at 10 CFR 61.2) and chemical waste materials generated in the laboratories serviced by the contracts administered by FDA, if the waste is disposed of in compliance with all applicable Federal, State, and local requirements.

§ 25.31 Human drugs and biologics.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

(b) Action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph, if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.

(c) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Withdrawal of approval of an NDA or an abbreviated application.

(e) Action on an IND.

(f) Testing and certification of batches of an antibiotic or insulin.

(g) Testing and release by the Center for Biologics Evaluation and Research of lots or batches of a licensed biologic product.

(h) Issuance, revocation, or amendment of a monograph for an antibiotic drug.

(i) Establishment of bioequivalence requirements for a human drug or a comparability determination for a biologic product subject to licensing.

(j) Issuance, revocation, or amendment of a standard for a biologic product.

(k) Revocation of a license for a biologic product.

(l) Action on an application for marketing approval for marketing of a biologic product for transfusable human blood or blood components and plasma.

§ 25.32 Foods, food additives, and color additives.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Issuance, amendment, or repeal of a food standard.

(b) Action on a request for exemption for investigational use of a food additive if the food additive to be shipped under the request is intended to be used for clinical studies or research.

(c) Approval of a color additive petition to change a provisionally listed color additive to permanent listing for use in food, drugs, devices, or cosmetics.

(d) Testing and certification of batches of a color additive.

(e) Issuance of an interim food additive regulation.

(f) Affirmation of a food substance as GRAS for humans or animals on FDA's initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter, and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, if the substance or food ingredient is already marketed in the United States for the proposed use.

(g) Issuance and enforcement of regulations relating to the control of communicable diseases or to interstate conveyance sanitation under parts 1240 and 1250 of this chapter.

(h) Approval of a request for diversion of adulterated or misbranded food for humans or animals to use as animal feeds.

(i) Approval of a food additive petition, GRAS affirmation petition, or the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, when the substance is present in finished food-packaging material at not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material.

(j) Approval of a food additive petition, GRAS affirmation petition, or the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, when the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

(k) Approval of a food additive, color additive, or GRAS petition for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.

(l) Approval of a petition for color additives used in contact lenses, sutures, filaments used as supporting haptics in intraocular lenses, bone cement, and in other FDA-regulated products having similarly low levels of use.

(m) Action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics.

(n) Issuance, amendment, or revocation of a regulation pertaining to infant formulas.

(o) Approval of a food additive petition for the intended expression product(s) present in food derived from new plant varieties.

(p) Issuance, amendment, or revocation of a regulation in response to a reference amount petition as described in § 101.12(h) of this chapter, a nutrient content claim petition as described in § 101.69 of this chapter, a health claim petition as described in § 101.70 of this chapter, or a petition pertaining to the label declaration of ingredients as described in § 101.103 of this chapter.

(q) Approval of a food additive petition or the granting of a request for an exemption from regulation as a food additive under § 170.39 of this chapter for a substance registered by the Environmental Protection Agency under FIFRA for the same use requested in the petition.

(r) Approval of a food additive, color additive, or GRAS affirmation petition for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

§ 25.33 Animal drugs.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NADA, abbreviated application, or a supplement to such applications, if the action does not increase the use of the drug. Actions to which this categorical exclusion applies may include:

(1) An animal drug to be marketed under the same conditions of approval as a previously approved animal drug;

(2) A combination of previously approved animal drugs;

(3) A new premix or other formulation of a previously approved animal drug;

(4) Changes specified in § 514.8 (a)(5), (a)(6), or (d) of this chapter;

(5) A change of sponsor;

(6) A previously approved animal drug to be contained in medicated feed blocks under § 510.455 of this chapter or as a liquid feed supplement under § 558.5 of this chapter; or

(7) Approval of a drug for use in animal feeds if such drug has been approved under § 514.2 or 514.9 of this chapter for other uses.

(b) [Reserved]

(c) Action on an NADA, abbreviated application, or a supplement to such applications, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Action on an NADA, abbreviated application, or a supplement to such applications, for:

(1) Drugs intended for use in nonfood animals;

(2) Anesthetics, both local and general, that are individually administered;

(3) Nonsystemic topical and ophthalmic animal drugs;

(4) Drugs for minor species, including wildlife and endangered species, when the drug has been previously approved for use in another or the same species where similar animal management practices are used; and

(5) Drugs intended for use under prescription or veterinarian's order for therapeutic use in terrestrial species.

(e) Action on an INAD.

(f) Action on an application submitted under section 512(m) of the act.

(g) Withdrawal of approval of an NADA or an abbreviated NADA.

(h) Withdrawal of approval of a food additive petition that reduces or eliminates animal feed uses of a food additive.

§ 25.34 Devices and electronic products.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on a device premarket notification submission under subpart E of part 807 of this chapter.

(b) Classification or reclassification of a device under part 860 of this chapter.

(c) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard.

(d) Approval of a PMA or a notice of completion of a PDP or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device.

(e) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(f) Issuance of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(g) Action on an application for an IDE or an authorization to commence a clinical investigation under an approved PDP.

(h) Issuance of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

Subpart D—Preparation of Environmental Documents

§ 25.40 Environmental assessments.

(a) As defined by CEQ in 40 CFR 1508.9, an EA is a concise public document that serves to provide sufficient evidence and analysis for an agency to determine whether to prepare an EIS or a FONSI. The EA shall include brief discussions of the need for the proposal, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted. An EA shall be prepared for each action not categorically excluded in §§ 25.30, 25.31, 25.32, 25.33, or 25.34. The EA shall focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles and shall be a concise, objective, and well-balanced document that allows the public to understand the agency's decision. If potentially adverse environmental impacts are identified for an action or a group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The use of a scientifically justified tiered testing approach, in which testing may be stopped when the results suggest that no significant impact will occur, is an acceptable approach.

(b) Generally, FDA requires an applicant to prepare an EA and make necessary corrections to it. Ultimately, FDA is responsible for the scope and content of EA's and may include additional information in environmental documents when warranted.

(c) Information concerning the nature and scope of information that an applicant or petitioner shall submit in an EA may be obtained from the center or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA EA guidance documents, which provide additional advice on how to comply with FDA regulations.

(d) Consistent with 40 CFR 1500.4(j) and 1502.21, EA's may incorporate by reference information presented in other documents that are available to FDA and to the public.

(e) The agency evaluates the information contained in an EA and any public input to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS or a FONSI will be prepared. The responsible agency official designated in part 5 of this chapter as responsible for the underlying action examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and

ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action.

§ 25.41 Findings of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a FONSI is a document prepared by a Federal agency stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) The agency official(s) responsible for approving the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusion not to prepare an EIS for the action under consideration.

§ 25.42 Environmental impact statements.

(a) As defined by CEQ regulations (40 CFR 1508.11) and section 102(2)(C) of NEPA, an EIS should be a clear, concise, and detailed written statement describing:

(1) The environmental impacts of a proposed action;

(2) Any adverse effects that cannot be avoided if the action is implemented;

(3) Alternatives to the action;

(4) The relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity; and

(5) Any irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented.

(b) The CEQ regulations (40 CFR 1501.7 and part 1502) describe the process for determining the scope of an EIS and provide detailed requirements for the preparation of draft and final EIS's. CEQ format and procedures for preparing EIS shall be followed.

(c) Under the conditions prescribed in 40 CFR 1502.9, the agency will prepare a supplement for a draft or final EIS and introduce the supplement into the administrative record.

§ 25.43 Records of decision.

(a) In cases requiring environmental impact statements, at the time of its decision, the agency shall prepare a concise public record of decision.

(b) The record of decision shall:

(1) State what the decision was;

(2) Identify and discuss alternatives considered by the agency in reaching its decision;

(3) State whether all practicable means to avoid or minimize environmental harm have been adopted, and if not, why not; and

(4) Summarize the program for monitoring and enforcing the practicable means adopted to avoid or minimize the environmental harm.

§ 25.44 Lead and cooperating agencies.

For actions requiring the preparation of an EIS, FDA and other affected Federal agencies will agree which will be the lead agency and which will be the cooperating agencies. The responsibilities of lead agencies and cooperating agencies are described in the CEQ regulations (40 CFR 1501.5 and 1501.6, respectively). If an action affects more than one center within FDA, the Commissioner of Food and Drugs will designate one of these units to be responsible for coordinating the preparation of any required environmental documentation.

§ 25.45 Responsible agency official.

(a) The person designated in part 5 of this chapter as the responsible agency official for the underlying action is responsible for preparing environmental documents or ensuring that they are prepared.

(b) The responsible agency official will weigh any environmental impacts of each alternative course of action, including possible mitigation measures, and will balance environmental impacts with the agency's objectives in choosing an appropriate course of action. The weighing of any environmental impacts of alternatives in selecting a final course of action will be reflected in the agency's record of formal decisionmaking as required by 40 CFR 1505.2.

Subpart E—Public Participation and Notification of Environmental Documents

§ 25.50 General information.

(a) To the extent actions are not protected from disclosure by existing law applicable to the agency's operation, FDA will involve the public in preparing and implementing its NEPA procedures and will provide public notice of NEPA-related hearings, public meetings, and the availability of environmental documents.

(b) Many FDA actions involving investigations, review, and approval of applications, and premarket notifications for human drugs, animal drugs, biologic products, and devices are protected from disclosure under the Trade Secret Act, 18 U.S.C. 1905, and 301(j) of the act. These actions are also protected from disclosure under FDA's regulations including part 20, §§ 312.130(a), 314.430(b), 514.11(b), 514.12(a), 601.50(a), 601.51(a), 807.95(b), 812.38(a), and 814.9(b) of this chapter. Even the existence of applications for human drugs, animal drugs, biologic products, and devices is protected from disclosure under these regulations. Therefore, unless the existence of applications for human drugs, animal drugs, biologic products, or premarket notification for devices has been made publicly available, the release of the environmental document before approval of human drugs, animal drugs, biologic products, and devices is inconsistent with statutory requirements imposed on FDA. Appropriate environmental documents, comments, and responses will be included in the administrative record to the extent allowed by applicable laws.

§ 25.51 Environmental assessments and findings of no significant impact.

(a) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in the portion of environmental documents that is made public. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner shall submit such data and information separately in a confidential section and shall summarize the confidential data and information in the EA to the extent possible.

(b) FONSI's and EA's will be available to the public in accordance with 40 CFR 1506.6 as follows:

(1) When the proposed action is the subject of a notice of proposed rulemaking or a notice of filing published in the **Federal Register**, the notice shall state that no EIS is necessary and that the FONSI and the EA are available for public inspection at FDA's Dockets Management Branch. If the responsible agency official is unable to complete environmental consideration of the proposed action before a notice of filing of a food or color additive petition is required to be published under the act, and if the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the final regulation rather than the notice of filing shall state that no EIS is necessary and that the FONSI and the EA are available upon request and filed in FDA's Dockets Management Branch.

(2) For actions for which notice is not published in the **Federal Register**, the FONSI and the EA shall be made available to the public upon request according to the procedures in 40 CFR 1506.6.

(3) For a limited number of actions, the agency may make the FONSI and EA

available for public review (including review by State and areawide information clearinghouses) for 30 days before the agency makes its final determination whether to prepare an EIS and before the action may begin, as described in 40 CFR 1501.4(e). This procedure will be followed when the proposed action is, or is closely similar to, one that normally requires an EIS or when the proposed action is one without precedent.

§ 25.52 Environmental impact statements.

(a) If FDA determines that an EIS is necessary for an action involving investigations or approvals for drugs, animal drugs, biologic products, or devices, an EIS will be prepared but will become available only at the time of the approval of the product. Disclosure will be made in accordance with 40 CFR 1506.6 and part 20 of this chapter. The EIS will in all other respects conform to the requirements for EIS's as specified in 40 CFR part 1502 and 1506.6(f).

(b) Comments on the EIS may be submitted after the approval of the drug, animal drug, biologic product, or device. Those comments can form the basis for the agency to consider beginning an action to withdraw the approval of applications for a drug, animal drug, or biologic product, or to withdraw premarket notifications or premarket approval applications for devices.

(c) In those cases where the existence of applications and premarket notifications for drugs, animal drugs, biologic products, or devices has already been disclosed before the agency approves the action, the agency will make diligent effort (40 CFR 1506.6) to involve the public in preparing and implementing the NEPA procedures for EIS's while following its own disclosure requirements including those listed in part 20, §§ 312.130(b), 314.430(d), 514.11(d), 514.12(b), 601.51(d), 807.95(e), 812.38(b), and 814.9(d) of this chapter.

(d) Draft and final EIS's, comments, and responses will be included in the administrative record and will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

Subpart F—Other Requirements

§ 25.60 Environmental effects abroad of major agency actions.

(a) In accordance with Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions'' of January 4, 1979 (44 FR 1957, January 9, 1979), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

(1) Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere.

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine, in accordance with section 2–3 of the Executive Order, whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine, in accordance with section 2–4(a) and (b) of the Executive Order, whether the subject action calls for:

(1) An EIS;

(2) A bilateral or multilateral environmental study; or

(3) A concise environmental review.

(d) In preparing environmental documents under this subpart, the responsible official shall:

(1) Determine, as provided in section 2–5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and modification in contents, timing, and availability of documents.

(2) Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.

PART 71—COLOR ADDITIVE PETITIONS

7. The authority citation for 21 CFR part 71 continues to read as follows:

Authority: Secs. 201, 402, 409, 501, 505, 506, 507, 510, 512–516, 518–520, 601, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 351, 355, 356, 357, 360, 360b–360f, 360h–360j, 361, 371, 379e, 381); secs. 215, 351 of the Public Health Service Act (42 U.S.C. 216, 262).

8. Section 71.1 is amended in paragraph (c) by revising item J to read as follows:

§ 71.1 Petitions.

* * * * *

(c) * * *

J. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

PART 101—FOOD LABELING

9. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

10. Section 101.12 is amended by revising paragraph (h)(12) to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(h) * * *

(12) A claim for categorical exclusion under § 25.30 or 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter; and

* * * * *

11. Section 101.69 is amended by revising paragraph (h), item E of paragraph (m)(1), item C of paragraph (n)(1), and item C of paragraph (o)(1) to read as follows:

§ 101.69 Petitions for nutrient content claims.

* * * * *

(h) All petitions submitted under this section shall include either a claim for a categorical exclusion under § 25.30 or 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

(m) * * *

(1) * * *

E. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

(n) * * *

(1) * * *

C. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

(o) * * *

(1) * * *

C. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

12. Section 101.70 is amended in paragraph (f) by revising item F to read as follows:

§ 101.70 Petitions for health claims.

* * * * *

(f) * * *

F. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

PART 170—FOOD ADDITIVES

13. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

14. Section 170.35 is amended by revising paragraph (c)(1)(viii) to read as follows:

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c) * * *

(1) * * *

(viii) A claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

15. Section 170.39 is amended by revising the second sentence in paragraph (c)(6) and the seventh sentence in paragraph (e) to read as follows:

§ 170.39 Threshold of regulation for substances used in food-contact articles.

* * * * *

(c) * * *

(6) * * * The request should contain either a claim for categorical exclusion as specified in § 25.32 of this chapter or an environmental assessment as specified in § 25.40 of this chapter.

* * * * *

(e) * * * For actions requiring an environmental assessment, the agency's finding of no significant impact and the evidence supporting that finding, contained in the petitioner's environmental assessment, also will be available for public inspection at the Dockets Management Branch in accordance with § 25.51(b)(2) of this chapter. * * *

* * * * *

PART 171—FOOD ADDITIVE PETITIONS

16. The authority citation for 21 CFR part 171 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

17. Section 171.1 is amended in paragraph (c) by revising item H to read as follows:

§ 171.1 Petitions.

* * * * *

(c) * * *

H. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

18. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

19. Section 312.23 is amended by revising paragraph (a)(7)(iv)(*e*) to read as follows:

§ 312.23 IND content and format.

(a) * * *

(7) * * *

(iv) * * *

(E) *Environmental analysis requirements.* A claim for categorical exclusion under § 25.30 or 25.31 or an environmental assessment under § 25.40.

* * * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

20. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

21. Section 314.50 is amended by revising paragraph (d)(1)(iii) to read as follows:

§ 314.50 Content and format of an application.

* * * * *

(d) * * *

(1) * * *

(iii) *Environmental impact.* The application is required to contain either a claim for categorical exclusion under § 25.30 or 25.31 of this chapter or an environmental assessment under § 25.40 of this chapter.

22. Section 314.101 is amended by revising paragraph (d)(4) to read as follows:

§ 314.101 Filing an application and an abbreviated antibiotic application and receiving an abbreviated new drug application.

* * * * *

(d) * * *

(4) The applicant fails to submit a complete environmental assessment, which addresses each of the items specified in the applicable format under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.31 of this chapter.

* * * * *

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

23. The authority citation for 21 CFR part 511 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 360b, 371).

24. Section 511.1 is amended by revising paragraph (b)(10) to read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the act.

* * * * *

(b) * * *

(10) The sponsor shall submit either a claim for categorical exclusion under § 25.30 or § 25.33 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

25. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: Secs. 501, 502, 512, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 379e, 381).

26. Section 514.1 is amended by revising paragraph (b)(14) to read as follows:

§ 514.1 Applications.

* * * * *

(b) * * *

(14) *Environmental assessment.* The applicant is required to submit either a claim for categorical exclusion under § 25.30 or § 25.33 of this chapter or an

environmental assessment under § 25.40 of this chapter.

* * * * *

27. Section 514.8 is amended by revising the fourth sentence of paragraph (a)(1) to read as follows:

§ 514.8 Supplemental new animal drug applications.

(a)(1) * * * A supplemental application shall be accompanied by either a claim for categorical exclusion under § 25.30 or § 25.33 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

28. Section 514.110 is amended by revising paragraph (b)(10) to read as follows:

§ 514.110 Reasons for refusing to file applications.

* * * * *

(b) * * *

(10) The applicant fails to submit a complete environmental assessment under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.33 of this chapter.

* * * * *

29. Section 514.111 is amended by revising paragraph (a)(9) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(9) The applicant fails to submit an adequate environmental assessment under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.33 of this chapter.

* * * * *

PART 570—FOOD ADDITIVES

30. The authority citation for 21 CFR part 570 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

31. Section 570.35 is amended by revising paragraph (c)(1)(viii) to read as follows:

§ 570.35 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c) * * *

(viii) A claim for categorical exclusion under § 25.30 or 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

PART 571—FOOD ADDITIVE PETITIONS

32. The authority citation for 21 CFR part 571 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371); sec. 301 of the Public Health Service Act (42 U.S.C. 241).

33. Section 571.1 is amended in paragraph (c) by revising item H to read as follows:

§ 571.1 Petitions.

* * * * *

(c) * * *

H. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

PART 601—LICENSING

34. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 513–516, 518–520, 701, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381); secs. 215, 301, 351, 352 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461).

35. Section 601.2 is amended by revising the third sentence in paragraph (a) and the second sentence in paragraph (c)(2) to read as follows:

§ 601.2 Applications for establishment and product licenses; procedures for filing.

(a) * * * The applicant shall also include either a claim for categorical exclusion under § 25.30 or 25.31 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

(c) * * *

(2) * * * The applicant shall also include either a claim for categorical exclusion under § 25.30 or 25.31 of this chapter or an environmental assessment under § 25.40 of this chapter.

* * * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

36. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

37. Section 812.20 is amended by revising paragraph (b)(9) to read as follows:

§ 812.20 Application.

* * * * *

(b) * * *

(9) A claim for categorical exclusion under § 25.30 or 25.34 or an environmental assessment under § 25.40.

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

38. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: Secs. 501, 502, 503, 510, 513–520, 701, 702, 703, 704, 705, 721, 708, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379e, 381).

39. Section 814.20 is amended by revising paragraph (b)(11) to read as follows:

§ 814.20 Application.

* * * * *

(b) * * *

(11) An environmental assessment under § 25.20(n) prepared in the applicable format in § 25.40, unless the action qualifies for exclusion under § 25.30 or § 25.34. If the applicant believes that the action qualifies for exclusion, the PMA shall under § 25.15(a) and (d) provide information that establishes to FDA's satisfaction that the action requested is included within the excluded category and meets the criteria for the applicable exclusion.

* * * * *

Dated: May 9, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–19566 Filed 7–28–97; 8:45 am]

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Federal Register

Tuesday
July 29, 1997

Part III

Department of Transportation

National Highway Traffic Safety Administration

Denial of Petition for a Defect Investigation; Notice

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Denial of Petition for a Defect Investigation

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a petition submitted to NHTSA under 49 U.S.C. 30162, requesting that the agency commence a proceeding to determine the existence of a defect related to motor vehicle safety.

FOR FURTHER INFORMATION CONTACT: Mr. John Hinch, Senior Engineering Advisor, Office of Defects Investigation, NHTSA, 400 Seventh Street, SW, Washington, DC 20590. Telephone: (202) 366-5195.

SUPPLEMENTARY INFORMATION: By letter dated December 23, 1996, David Pittle, of Consumers Union of United States, Inc. (CU), petitioned NHTSA to investigate the alleged propensity of model year (MY) 1995–1996 Isuzu Trooper and 1996 Acura SLX sport utility vehicles (subject vehicles) to roll over during evasive maneuvering and to issue an order concerning the notification and remedy of an alleged safety-related defect in those vehicles.

The petitioner alleges that the subject vehicles have an ''unreasonable risk of rollover associated with emergency maneuvers.'' In support of this allegation the petitioner argues that: (1) Tests conducted at the petitioner's test facility indicate that the subject vehicles will tip up when driven through the CU ''short course,'' which is a portion of the testing used by CU to evaluate the vehicle's emergency handling rating; (2) Tests of 3 peer vehicles, conducted at the same time, showed that these vehicles (Toyota 4–Runner, Nissan Pathfinder, and Chevrolet Tahoe) had a distinctively different performance—they did not tip up when driven through the ''short course,'' (3) Computer simulation, conducted by independent experts retained by CU, indicates that the subject vehicles will tip up while driving through a course like the CU short course; and (4) Additional computer simulation indicates that the rollover propensity of the subject vehicles could be reduced by increasing the front roll stiffness, which could be accomplished by increasing the size of the front stabilizer bar.

CU supplemented its petition with additional information on several occasions. Other relevant information was provided by Isuzu Motors America, Inc., and American Suzuki Motor Corporation.

NHTSA has reviewed all information brought to its attention, conducted tests of the subject vehicles and peer vehicles, and reviewed crash data bases and Office of Defects Investigation's consumer complaint data base. The results of this review and analysis are published in a petition analysis report: ''Petition Analysis DP96–011: Petition for Defect Investigation Concerning the Rollover Propensity of MY 1995–96 Isuzu Trooper and 1996 Acura SLX Vehicles,'' June 1997. This report is published in its entirety as an appendix to this notice.

For the reasons presented in the petition analysis report, there is no reasonable possibility that an order concerning the notification and remedy of a safety-related defect in the subject vehicles would be issued at the conclusion of an investigation. Therefore, in view of the need to allocate and prioritize NHTSA's limited resources to best accomplish the agency's safety mission, the petition is denied.

Issued on: July 24, 1997.

Kenneth N. Weinstein,

Associate Administrator for Safety Assurance.

Authority: 49 U.S.C. 30162(a); delegations of authority at 49 CFR 1.50 and 501.8

BILLING CODE 4910–59–M

Petition Analysis DP96-011: Petition for Defect Investigation Concerning Rollover Propensity of MY 1995-96 Isuzu Trooper and 1996 Acura SLX Vehicles

June 1997

Office of Defects Investigation
NHTSA
400 7th St., SW
Washington, DC 20590

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PETITION ANALYSIS — DP96-011[1]

1.0 INTRODUCTION

Consumers Union of United States, Inc. (CU) (petitioner), 101 Truman Avenue, Yonkers, New York 10703 petitioned the National Highway Traffic Safety Administration (NHTSA) by letter dated August 20, 1996, requesting that an investigation be conducted to determine whether to issue an order concerning the notification and remedy of a defect in model year 1995 and 1996 Isuzu Trooper and 1996 Acura SLX sport utility vehicles (subject vehicles) because of concerns related to their rollover propensity. The petition was supplemented on December 23, 1996, with CU supplying additional information for the agency to consider. The CU petition also requested the agency to commence a rulemaking proceeding related to rollover propensity. That aspect of the CU petition has been addressed in a separate notice.

NHTSA has received submissions in this proceeding from several parties, including CU, Isuzu Motors America, Inc. (Isuzu), and American Suzuki Motor Corporation (Suzuki). Much of the material in these submissions is not directly related to the issue of whether to grant the petition. However, all of the submissions in their entirety have been placed in NHTSA's public file for this petition, DP96-011.

ODI considered all available relevant information in deciding whether to grant or deny the petition. In this case, this included data (including test reports and simulation results) supplied by CU, Isuzu, and Suzuki. In addition, NHTSA conducted a vehicle test program in which the subject vehicles' performance was compared to that of a peer vehicle and analyzed crash data and ODI complaint data. The following sections present a description of the information developed during the petition analysis.

2.0 PREVIOUS INQUIRIES AND INVESTIGATIONS BY NHTSA INTO ALLEGED ROLLOVER DEFECTS

In October 1979 and July 1981, NHTSA's Office of Defects Investigation (ODI) received two petitions for defect investigations concerning the stability of Jeep CJ vehicles. Both these petitions were denied due to the lack of specific information indicating that there was a defect that caused the vehicles to roll over.

In 1988, ODI received two petitions for a defect investigation regarding the alleged rollover propensity of 1986 through 1988 Suzuki Samurai vehicles, including convertible and Suzuki "variants" of the Samurai, the SJ410 and LJ80 models (DP88-011 and DP88-019). NHTSA also denied these petitions, primarily because the available information did not show that the rollovers

[1] This petition analysis is based on work performed by John Hinch of NHTSA's Office of Defects Investigation (ODI) and Gavin Howe of the Transportation Research Center, Inc., under contract to NHTSA.

were caused by a defect in the vehicle rather than by the driver and/or environmental factors. NHTSA concluded that: 1) The rollover crash involvement of the Samurai was no worse than that of most other light utility vehicles; 2) Occupant ejection is the primary cause of fatal and serious injuries in a rollover; 3) The Samurai had a track width to center of gravity (cg) ratio higher (better) than that of most other light utility vehicles. This ratio has been demonstrated to have a fundamental effect on the rollover propensity of vehicles; 4) The likelihood of a rollover is dependent on a variety of conditions present at any given moment, including vehicle condition, road/ground surface, topography, and vehicle speed; 5) Testing indicated that vehicle control was not a problem when the Suzuki vehicles were driven by experienced drivers. However, the short wheelbase, narrow track width, and low vehicular mass could cause an inexperienced driver to over-react to a given situation and induce rollover; 6) The test procedures for assessing the rollover propensity of vehicles existing during the time period the petition was considered were unsatisfactory identifiers of relative rollover propensity because they did not allow repeatable, reproducible results; and 7) The lack of utility vehicle driving experience exhibited by the Samurai drivers was the most important factor in many of the rollover events reviewed by the agency.

ODI conducted investigation EA89-013 concerning 1984-1989 Ford Bronco II sport utility vehicles. This investigation was opened in response to a defect petition, DP88-020. A peer analysis of rollover rates showed the Bronco II to be similar to other sport utility vehicles, as measured using the metric of first-event rollovers per single vehicle crash. ODI closed this investigation in October 1990, because "there appears no reasonable expectation that further investigation would lead to a determination of the existence of a safety-related defect with respect to any of the allegations regarding the propensity of the Bronco II to roll over."

In 1996 ODI was again petitioned to open a defect investigation into the Suzuki Samurai's rollover propensity. The petitioner alleged that Samurai convertibles have high rollover propensity, as reflected by their low static stability factor, and, when loaded with occupants, the vehicle is even less stable. After reviewing the materials presented in that petition and other available data and information, the agency concluded that it was unlikely that further investigation of alleged Samurai convertible rollover propensity would enable NHTSA to identify a safety-related defect. The petition (DP96-004) was therefore denied.

3.0 ALLEGED DEFECT

CU alleges that the 1995 and 1996 Isuzu Troopers and 1996 Acura SLX have an "unreasonable risk of rollover associated with emergency maneuvers." In support of this allegation, CU argues that:

a. Tests conducted at CU's test facility indicate that the subject vehicles will tip up when driven through the CU "short course," which is a portion of the testing used by CU to

evaluate the emergency handling capability of various vehicles. Based on the outcome of these tests, CU rated the subject vehicles as "Not Acceptable;"[2]

b. Three peer vehicles tested at the same time (Toyota 4-Runner, Nissan Pathfinder, and Chevrolet Tahoe) did not tip up when driven through the CU short course;

c. Computer simulation, conducted by independent experts, indicates that the subject vehicles will tip up when driven through a course like the CU short course; and

d. Additional computer simulation indicates that the subject vehicles' rollover propensity could be reduced by increasing the front roll stiffness, such as by increasing the size of the front stabilizer bar.

4.0 VEHICLE INFORMATION

4.1 Vehicles Involved

Table 1 presents the number of subject vehicles sold in the United States, as of August 31, 1996.

Table 1. Sales of Subject Vehicles in U.S. (as of August 31, 1996).

Model Year	Trooper	Acura SLX	Total
1995	22,508	--	22,508
1996	13,810	2,779	16,589
Grand Total			39,097

4.2 Subject Vehicle Description

The Isuzu Trooper underwent a major redesign in MY 1992, in which the size of the vehicle was increased. For MY 1995, Isuzu modified the vehicle slightly. This configuration represents the current generation of the Trooper. The Honda Acura SLX vehicle is the same as the 1996 Trooper, i.e., it has the same, or nearly the same, overall size, weight, engine, tires, etc., with some changes in trim.

The subject vehicles are equipped with four-wheel drive. The front suspension consists of upper and lower control arms, supporting the wheel ends with ball joints. The front suspension incorporates torsion bar springs, a stabilizer bar, and shock absorbers. The rear suspension consists of a solid axle, supported by coil springs. Two trailing links, one on each side, are

[2] CU determines whether a vehicle is considered "Not Acceptable" based on a committee review of a variety of factors, including drivers' impressions, test director oversight, review of movies, whether the tip-up was a repeatable occurrence, etc.

mounted low on the housing. A third trailing center link is mounted high on the rear-end housing. These links control the fore-aft motion and rotation of the axle. A lateral rod is installed to control the lateral motion of the housing. The rear suspension also has a stabilizer bar.

The subject vehicles have disk brakes on the front and rear axles. They are also equipped with a 4 wheel anti-lock brake system. The vehicles have 16-inch wheels with P245/70R16 tires. The tires are supplied by two manufacturers: Goodyear and Bridgestone.

4.3 Subject Vehicle Parameters

The subject vehicles' basic vehicle parameters are presented in Table 2.

Table 2. Basic Subject Vehicle Parameters.

Parameter	Value
Lightly loaded weight	4467 pounds
Wheelbase	108.8 inches
Track Width, front/rear	59.6/59.8 inches
Height	70.5 inches
Center of gravity, from front axle	52.2 inches
Center of gravity, above ground	27.5 inches

Table 3 lists additional vehicle parameters, including inertia parameters, center of gravity (cg) location, and static stability factor (SSF), for several different vehicle configurations. A more complete listing is presented in "Tests Concerning Rollover Propensity of 1995-96 Isuzu Trooper and 1996 Acura SLX," Vehicle Research and Test Center, NHTSA, 1997 (VRTC report), which documents the sources for this data.

Table 3 indicates the following:

1) The effect of vehicle loading: Fully loading a vehicle causes significant increases in the roll and yaw mass moments of inertia (Ixx and Izz). It also increases the cg height and lowers the SSF.

2) The effect of different outrigger designs: The increase in the Izz due to fully loading the vehicle is similar to the increase that occurs when the CU outriggers are used with a driver present, while the increase in the Ixx due to a full load is significantly less. The VRTC outriggers cause a moderate increase (about 10 percent) in the Ixx and a negligible increase (about 2 percent) in the Izz compared to the base vehicle. The CU outriggers cause a very large increase (about 30 percent) in the Ixx and a large increase (about 20 percent) in the Izz compared to the base vehicle.

Since the CU short course requires the vehicle to be steered quickly, and since these quick steering maneuvers generate angular accelerations (both in yaw and roll) that are proportional to the mass moments of inertia, changes in a vehicle's mass moments of inertia could have a significant effect on the vehicle's performance on the course.

Table 3. Subject Vehicle Weight, Inertia, CG Height, and SSF.

Source	Vehicle Configuration	Weight (lb.)	Ixx[a] (ft.lb.s^2)	Izz[b] (ft.lb.s^2)	CG Height (in.)	SSF[c,d]
VRTC	1996 Acura SLX w/ 1 occ	4467	636	2869	27.5	1.09
	1996 Acura SLX w/ 4 occ + cargo to GVWR	5506	735	3425	27.9	1.07
	1996 Acura SLX	4289	611	2878	27.2	1.10
	1996 Acura SLX w/ VRTC outriggers	4402	675	2935	26.7	1.12
CU	1996 Isuzu Trooper	4448	654	2942	27.5	1.09
	1996 Isuzu Trooper w/ human driver	4614	687	2956	27.7	1.08
	1996 Isuzu Trooper w/ sandbag driver	4614	679	2946	27.7	1.08
	1996 Isuzu Trooper w/ sandbag driver and CU outriggers	4883	894	3460	27.3	1.10
Carr	1996 Isuzu Trooper	4496			27.5	1.10
	1996 Isuzu Trooper w/ instrumentation	4807			27.3	1.10
	[a] - Ixx = Roll Mass Moment of Inertia [b] - Izz = Yaw Mass Moment of Inertia [c] - SSF = Static Stability Factor = Track Width/(2 x CG Height) [d] - The measured track widths for subject vehicles were different, hence, vehicles with the same cg height have different SSF values.					

4.4 Comparison to Prior Trooper Models

4.4.1 1992-1994 Trooper Properties

Table 4 presents certain measured and calculated values for the 1994 Trooper, which is the same as the 1992 and 1993 Trooper.

Table 4. 1994 Trooper Weight, Inertia, CG Height, and SSF.

Source	Vehicle Configuration	Weight (lb.)	Ixx (ft.lb.s^2)	Izz (ft.lb.s^2)	CG Height (in.)	SSF
VRTC	1994 Isuzu Trooper w/ 1 occ	4465	617	2918	27.0	1.07
	1994 Isuzu Trooper w/ 4 occ + cargo to GVWR	5513	719	3345	27.7	1.04

4.4.2 Vehicle Modifications

Isuzu stated that it has not made any modifications to the subject vehicles that would affect their rollover susceptibility since the start of the 1995 model year. However, there were differences between the 1995 Troopers and earlier Troopers, including changes to several suspension parameters to make the vehicle's track width 60 mm wider. Increasing the track width tends to make a vehicle less prone to rollover, assuming there are no other changes. Table 5 describes the changes from the 1992-1994 model to the 1995 and 1996 models.

4.4.3 Effect of Vehicle Modifications on Static Stability Metrics

As indicated in Tables 3, 4 and 5, the 1994 Trooper has a lower cg and a narrower track width than the 1996 Trooper/SLX. The SSF of the 1994 Trooper is slightly lower than that of the subject vehicles when calculated with just a driver and in the fully loaded condition. All other things being equal, this would indicate that the subject vehicles have a slightly lower rollover propensity than the 1994 Trooper.

Table 5. Changes in Trooper Design from 1992-1994 Model to 1995-1996 Model.

Component	Change
Track Width, Front	Increased from 1,455 to 1,515 mm
Track Width, Rear	Increased from 1,460 to 1,520 mm
Center of gravity	no change reported
Wheelbase	no change reported
Wheels	no change reported
Tires	Changed tread compound and internal structure
Front Suspension, Upper link	Length increased from 242 to 272 mm
Front Suspension, Upper link bushing	Rubber material was changed
Front Suspension, Lower link end	Length increased from 87 to 117 mm
Front Suspension, Outer track rod	Length increased from 299 to 329 mm
Front Suspension, Drive shaft	Length increased by 30 mm
Front Suspension, Torsion bar	Spring rate increased by increasing bar diameter from 25.0 to 26.6 mm
Front Suspension, Shock absorbers	Damping force @ 0.3 m/s decreased from 183/67 to 148/67 kgf (rebound/compression)
Front Suspension, Stabilizer bar	no change reported
Rear Suspension, Axle case	Length increased 30 mm
Rear Suspension, Axle shaft	Length increased 30 mm
Rear Suspension, Coil springs	Spring rate increased from 2.8 to 3.0 kgf/mm
Rear Suspension, Shock absorbers	Damping force @ 0.3 m/s decreased from 118/33 to 125/52 kgf (rebound/compression)
Rear Suspension, Stabilizer bar	no change reported

VRTC also had SEA, Inc. compute the Tilt Table Ratio (TTR) of the 1996 Acura SLX and the 1994 Isuzu Trooper. The tilt table measures the angle at which both "high side" tires of the vehicle lift off a platform when it is slowly tilted in roll. This angle is then used to compute the TTR. The results are summarized in Table 6, which also summarizes the comparative SSF data.[3] In both the single occupant and fully-loaded condition, the 1996 Acura SLX had a higher TTR than the 1994 Trooper, which, standing alone, would indicate a lower rollover propensity for the 1996 Acura SLX.

Table 6. Tilt Table Angle, TTR, and SSF for Several Vehicle Configurations.

Vehicle Configuration	Tilt Table Angle (deg)	TTR[a]	SSF
1996 Acura SLX w/ 1 occupant	42.6	.92	1.09
1996 Acura SLX w/ 4 occupants + cargo	40.0	.84	1.07
1994 Isuzu Trooper w/ 1 occupant	41.4	.88	1.07
1994 Isuzu Trooper w/ 4 occupants + cargo	38.7	.80	1.04

[a] - TTR = tan(Tilt Table Angle)

4.4.4 CU Rating of MY 1992 Trooper

In its November 1992 issue of Consumer Reports, CU rated the "Emergency Handling" capability of the 1992 Trooper as "Good." This rating was based on several tests, including the vehicle's performance on the CU short course.

5.0 COMPLAINTS AND LAWSUITS

5.1 Complaints to ODI and Manufacturers Regarding the Subject Vehicles

ODI has reviewed owner complaints received by ODI and Isuzu that may be related to the alleged defect in the subject vehicles. Except for a single complaint to Isuzu in April 1996, all complaints were received by Isuzu and ODI after the CU press release (August 21, 1996). This suggests that the relatively high number of complaints regarding the subject vehicles is due to the publicity generated by CU and other media reports. This reduces the reliability of comparisons with the number of complaints submitted to ODI regarding peer vehicles.

A total of 36 complaints have been received. These include 13 to ODI (as of April 18, 1997) and 23 non-duplicate complaints to Isuzu (as of March 21, 1997). Honda did not report any complaints associated with the Acura SLX vehicle, and none have been received by ODI.

[3] A more detailed discussion of this data can be found in the VRTC test report.

Owner complaints vary considerably, with some owners reporting the sensation of tip-up during driving, while others report rollovers. A tip-up sensation is hard to differentiate from a large body lean. (The Trooper leans seven to eight degrees during a hard turn, which feels dramatic, even when the wheels are on the ground.)

Of the 36 complaints, some indicated that there had been a crash prior to rollover, which may have contributed to the rollover event. Others were run-off-the-road rollover crashes, while others were of the crash avoidance type (of which the CU short course maneuver is an example). The events reported in the complaints are presented in Table 7.

Table 7. Distribution of Complaint by Type of Maneuver.

Type of Complaint	Number
Crash Avoidance (without rollover)	14
Crash Avoidance (with rollover)	4
Prior Crash	3
Loss of Control	6
Tip-up While Turning	8
Tip-up While Parked in Lot	1

Table 8 presents the complaints by source and model year.

Table 8. Subject Vehicle Complaint Distribution.

Model Year	ODI	Isuzu	Total
1995	5	17	22
1996	8	5	13
Unknown	0	1	1
Total	13	23	36

The complaints are fairly evenly distributed by failure date (the date of the alleged incident). Failure and complaint date data are presented in Figures 1 and 2.

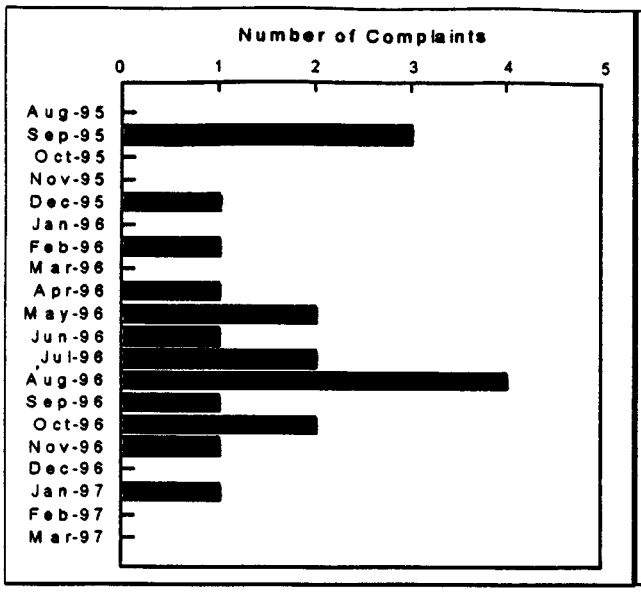

Figure 1. Failure Date Analysis, Subject Vehicles.

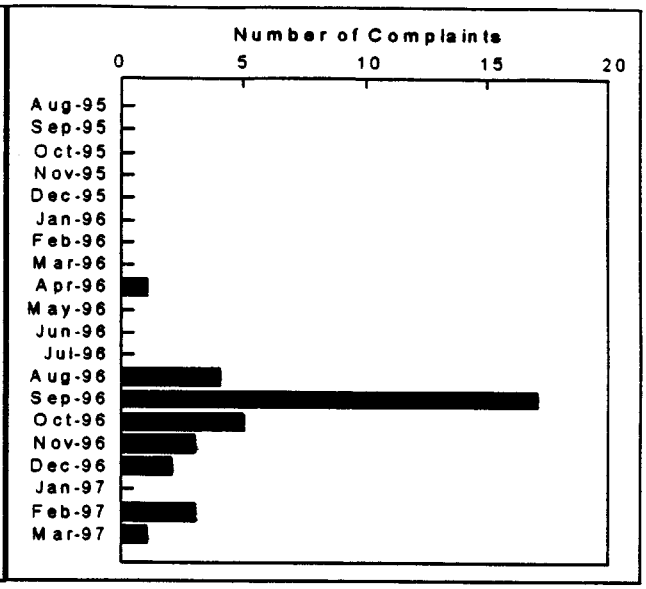

Figure 2. Complaint Date Analysis, Subject Vehicles.

5.2 Complaints to ODI Regarding the 1992-94 Trooper

ODI also received several tip-up complaints involving 1992-94 Troopers following the CU press conference. These consumers claimed that their vehicles were rollover sensitive. Of the five complaints, four involved rollovers.[4]

5.3 Lawsuits

As of March 21, 1997, Isuzu had been named as a defendant in five lawsuits related to the alleged defect. Four of these are class actions.

5.4 Analysis of Rollover Complaints Made to ODI Regarding MY 1994-1996 Vehicles

ODI analyzed its data base for all rollover complaints regarding 1994, 1995, and 1996 model year vehicles. These model years were selected so the vehicles that were being analyzed would be of the same approximate age as the subject vehicles.

Each complaint in the ODI data base is given a "Fault" code for cause and result. Each complaint that had a "cause fault" or "result fault" of "rollover" was individually reviewed to eliminate duplications and non-rollover crashes. 92 such complaints were identified. Table 9 shows the

[4] These complaints were received between August 26, 1996 and March 16, 1997.

distribution of these 92 complaints by model year. Also shown are rates adjusted for exposure years. Annual total vehicle production for these three years was fairly constant, 15.7, 15.2, and 15.3 million vehicles for 1994, 1995, and 1996, respectively, thus no adjustment for number of vehicles produced was made. This table indicates that the distribution of rollover complaints is fairly constant, when normalized by exposure years.

Table 9. ODI Complaint Distribution by MY for Fault Code = "Rollover," All Vehicles.

Model Year	Number of rollover complaints	Exposure Years	Rollover based on exposure (rollovers/year)
1994	51	3	17
1995	24	2	12
1996	17	1	17
Total	92	6	15

The type of vehicle involved in these complaints is presented in Table 10.

Table 10. Complaint Distribution by Vehicle Type for Fault Code = "Rollover," ODI Complaints.

Type of Vehicle	Number of Complaints
Sport Utility Vehicle	42
Car	29
Van	6
Light Truck	15

For each of these complaints, the alleged action of the vehicle just prior to the rollover was ascertained. In many cases, the reported rollover appears to have been caused by a vehicle malfunction, i.e., brake failure, tire failure, steering failure, etc. The distribution of vehicle actions associated with these complaints is shown in Table 11.

Table 11. Distribution of Vehicle Action Prior to Rollover for Fault Code = "Rollover," ODI Complaints.

Cause of event	Number of Complaints
Vehicle Induced	46
Crash Avoidance	3
Crash Prior to Rollover	9
Loss of Control	34

The three complaints for which ODI analysis indicated that the rollover had been preceded by a crash avoidance maneuver involved a 1996 Chevrolet C-1500 full-size pickup, 1995 Dodge Dakota mid-size pickup, and a 1995 Isuzu Trooper.

6.0 TESTING

CU submitted test data to support its petition. In addition, ODI received test data from Isuzu, Carr Engineering, Inc. (Carr) on behalf of Isuzu, and Suzuki. NHTSA conducted additional testing. This section of the petition analysis summarizes the results of this testing. Detailed results of the testing can be found in the public file.

The CU short course test, the results of which constitute the primary basis for this petition, is used as a check test to explore a vehicle's rollover resistance during an extreme maneuver. CU has been using the short course since 1988. CU tests all sport utility vehicles on the short course, as well as selected new entry vehicles such as minivans and compact pickup trucks.

CU performs routine handling, emergency handling, braking, acceleration, and other tests to determine vehicle ratings. For its "Emergency Handling" rating, CU uses a variety of tests, including their short and long crash avoidance courses. If a vehicle tips up substantially in tests on the short course, CU rates it "Not Acceptable," and does not give it an "Emergency Handling" rating. If, on the other hand, the vehicle does not tip up (or tips only slightly), the vehicle rating which was obtained through the series of tests is maintained.

Both Isuzu and Carr tested the subject vehicles using the CU short course. Carr also performed numerous other tests including CU long course, General Motors (GM) avoidance maneuver, man-off-the-street avoidance maneuver, GM - vehicle evasive performance test, System Technologies Inc. (STI) emergency lane change test, Nissan emergency avoidance maneuver, STI unexpected obstacle, Calspan man-off-the-street - surprise intrusion test, Hooker course, International Standards Organization (ISO) lane change, 100 & 200 foot and 18 meter slalom, high speed turn, 75 and 200 foot constant radius turn, 75 and 200 foot tangent turn, step steering, steering return, and panic braking. Carr did not test any peer vehicles, which reduces the value of these tests.

NHTSA conducted tests at the Transportation Research Center (TRC) located in East Liberty, Ohio and at the Uniform Tire Quality Grading (UTQG) facility located on the Goodfellow AFB in San Angelo, Texas. The primary focus of this test program involved driving vehicles through the CU short course. Vehicles tested included a 1996 Acura SLX and a 1996 Isuzu Trooper (supplied by CU). For comparison purposes, a peer vehicle (1994 Isuzu Trooper) was also tested. Additional testing was performed to determine the lateral transient response of the subject vehicles. Outrigger effects on vehicle performance were also analyzed.

6.1 Description of the CU Short Course

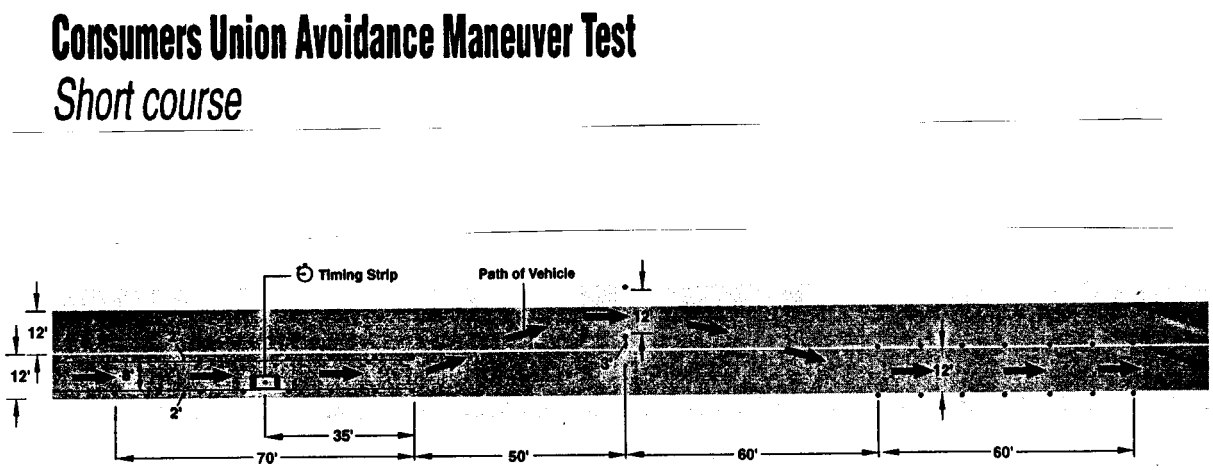

Figure 3. CU Short Course (from CU submission).

The CU short course is depicted in Figure 3. This course requires two lane changes. It consists of a 70-foot-long, 8-foot-wide entrance lane that is centered in the 12-foot-wide first (right) lane, a 50-foot-long area to make the first lane change, a set of gate cones at this 50-foot mark that are 12 feet apart, (with the right cone three feet over into the second (left) lane), a 60-foot-long area to make the second lane change (back to the original (right) lane), and a 12-foot-wide exit lane. CU drivers steer the vehicles through this course at successively higher entry speeds until the vehicle either plows out, slides out, or tips up. The vehicle's brakes are not applied, and the throttle is released as the vehicle passes the timing strip which measures the vehicle speed, located 35 feet before the end of the entrance lane (see Figure 3 for reference).

6.1.1 Relationship of CU Short Course Test Maneuver to Likely Real World Crash Avoidance Behavior

A driver who comes upon an expected obstacle will naturally try to avoid striking that obstacle. Such a driver generally will try to stop and/or turn.

Comparisons of Steering Inputs in CU Short Course Tests and in Real World Driving. A professional driver going through the CU short course turns the steering wheel hundreds of degrees at a very fast rate, exceeding 1,000 degrees/sec and often exceeding 1,300 degrees/second. CU provided complete steering profiles (prepared by Ian Jones) for only two

tests (See CU's December 23, 1996 submission, Attachment 7, Table 5). In a clean run[5] at 37.5 mph, CU driver KS turned the wheel at about 1,060 degrees/sec. In a high tip-up run, CU driver EAP turned the wheel at 1,020 degrees/sec.

In these same two tests, the steering inputs, as reported by Jones, for driver KS were 172 degrees left and 207 degrees right[6] for a total reverse steer of 379 degrees. The steering inputs employed by driver EAP were greater (179 degrees to the left and 389 degrees to the right, for a total reverse steer of 568 degrees).[7]

In the short course tests conducted by CU in which there was a tip-up, the steering inputs, as reported in CU's November 25, 1996 submission, were generally greater than those in non-tip-up runs. An analysis of the steering inputs on runs conducted by CU is presented in Figure 4. Note the difference in average steering input on the second steer (middle bar in each set) between the non-tip-up runs and the tip-up runs.

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[5] In its November 25, 1996 submission, CU provided a summary of the results of its summer 1996 short course testing. In that summary, CU indicated whether a particular run was "clean," which means that it negotiated the course without knocking down one or more cones. CU also indicated whether there was a "Wheel lift" or "Tip up" based on "Observer Comment:" "Wheel lift means a front wheel lifted, but not a rear wheel. Tip up means two wheels lifted off the pavement."

For each run in which there was a tip-up, CU characterized it as "Low," "Medium," or "High," based on the observer's "judgement:" "Low means off the pavement, but not too obvious (this is best judged from the video). Medium means that it was visually obvious to the observers, usually from several inches to a foot. High means more than one foot, including over onto the outriggers."

In summarizing the results of the VRTC testing, ODI essentially used this CU methodology, except it did not attempt to classify the severity of a tip-up.

[6] Right steer is measured from the initial (straight forward) steering wheel position; i.e., after the steering wheel has been rotated back to zero degrees.

[7] CU reported three different sets of steering inputs for these two runs: 1) supporting data for the petition (October 10, 1996); 2) a November 25, 1996 submission from Arnold and Porter; and 3) an analysis performed for CU by Ian Jones (December 23, 1996 letter from Arnold and Porter). A summary is presented below:

Driver	Speed	Result	October 10, 1996		November 25, 1996		December 23, 1996	
KS	37.5 mph	Clean	180° L	230° R	183° L	216° R	172° L	207° R
EAP	37.5 mph	High Tip-up	190° L	370° R	191° L	388° R	179° L	389° R

The Jones data (December 23, 1996) were used where the complete driving profiles for these two runs were analyzed. The November 25, 1996 steering inputs were used in analyses that address the entire set of CU tests.

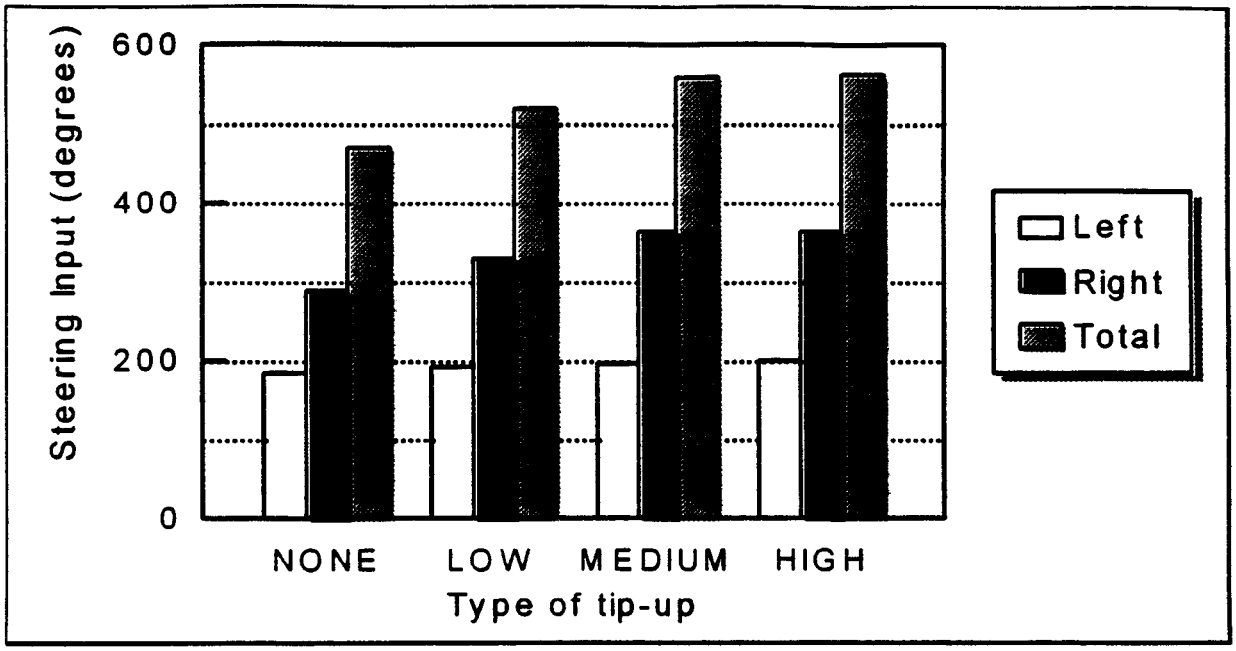

Figure 4. Average Steer Input for CU Tests of Subject Vehicles by Tip-up Result (November 25, 1996 submission).

In NHTSA's tests, in clean runs at 36 mph (Tests 55 & 57), left steers were about 205 degrees and right steers were about 250 degrees. The total reverse steer was about 460 degrees. In Carr's clean run at this speed (Test 34), left/right steers were 175 and 235 degrees respectively, for a total reverse steer of 410 degrees.

Several studies have been done of driver behavior in crash avoidance maneuvers. Average peak steering inputs from three of these studies are presented in Table 12.

Table 12. Steering Inputs and Rates in Crash Avoidance Maneuvers, from Three Studies.

Study	Steering Input (deg)	Steering Rate (deg/sec)
Calspan/GM (SAE-760777)	none reported	520 (all successful drivers) 800 (successful expert drivers) 850-1000 (loss of control)
Nissan (SAE-770130)	200-230 (first steer)	700-900
STI (DOT HS-801 407)	145 (first steer)	none reported

The Calspan/GM report ("Automobile Driver Characteristics and Capabilities—The Man-Off-The-Street," 1976, SAE # 760777) analyzed reaction to an Avoidance Maneuver. Average maximum steering rates for all successful drivers was about 520 degrees/sec. Rates of up to

1,000 degrees/sec were noted, but the higher rates were from drivers who lost control. This study did not report any steering wheel input angles.

The Nissan report ("Performance of Driver-Vehicle System in Emergency Avoidance," 1977, SAE # 770130) described maximum steering wheel angles for the first steer in emergency avoidance maneuvers that were concentrated in the range of 200 and 230 degrees. Maximum angular velocities for the same maneuver were concentrated in the range of 700 to 900 degrees/sec.

The STI report ("Automobile Controllability—Driver/Vehicle Response for Steering Control," February, 1975, DOT HS-801 407) presented data on several drivers' responses to an Unexpected Obstacle Avoidance Maneuver. The report states that the maximum steering inputs were about 145 degrees (it did not report steering rates).

These three studies suggest that the maximum steering input a driver is willing or able to make in response to an unexpected event are within the range of 145 to 230 degrees.[8] As demonstrated in the next section, during the tests conducted by CU drivers on the CU short course in which the subject vehicles tipped up, the initial (left) steering inputs were usually within this range (with one exception), but the second (right) steer was much greater. These studies also indicate that the rate a typical driver turns the wheel is not greater than 1,000 degrees/sec. The CU drivers, based on the two profiles supplied by CU, steered at rates up to 1060 degrees/sec. In tests on the CU short course conducted by NHTSA at speeds above 36 mph, the steering rate was generally in the range of 900 to 1,350 degrees/sec.

CU Short Course Sight and Stopping Distance.
Based on tire marks observed during testing, drivers executing the CU short course begin to turn the vehicle approximately 25 feet prior to reaching the last cone in the entrance gate, which is 50 feet from the obstacle cone. Thus, the CU short course simulates a situation where the driver starts to avoid an obstacle when (s)he is about 75 feet from the obstacle.[9]

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[8] These tests were conducted with MY mid-70's sedans. There are differences between these old sedans and the subject sport utility vehicles in terms of tires, steering gain, cg height, roll gradient, etc. These factors may have an effect on the reported maximum steering input angle and rate.

[9] Real drivers in everyday situations will not react as quickly as professional drivers on the CU short course. A real driver will lose time and distance between the point that (s)he first observe the obstacle and the point at which action is begun. This is due to the fact that the real driver will not be prepared as the test driver is. (S)he must observe the object, decide what to do, and finally take action.

Stopping distance for a typical vehicle with typical brakes on a dry road with coefficient of friction of 0.85 is shown in Figure 5. (These distances will vary with surface conditions.) Vehicles traveling up to 45 mph can stop before they reach an obstacle that is 75 feet away. Vehicles can stop in 60 to 70 feet from speeds typical of the entrance speed used by CU in its short course tests. Thus, a driver who applies the brakes at the point when the CU test drivers began to turn could safely stop before reaching the obstacle, without attempting to turn.

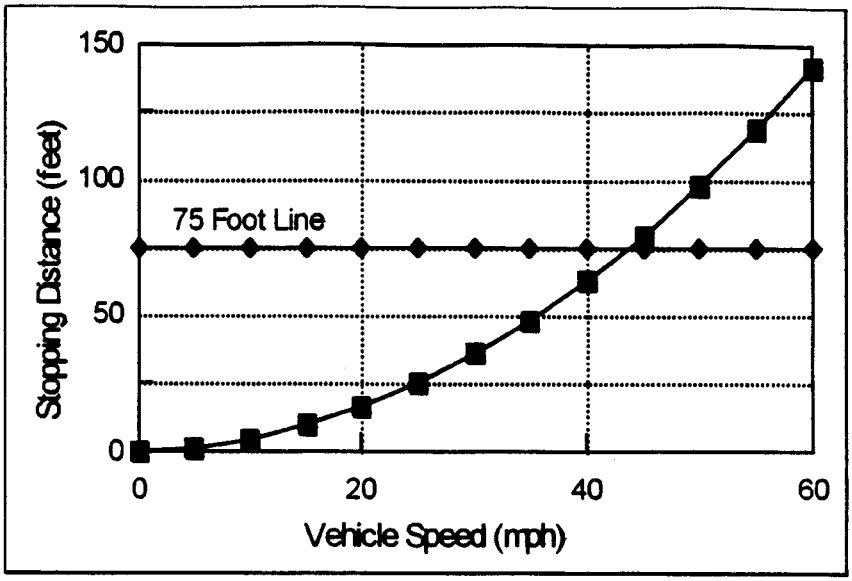

Figure 5. Stopping Distance vs. Vehicle Speed.

In the Surprise Intrusion Maneuver portion of the Calspan/GM study referred to above, about 34 subjects were tested. This test involves throwing a plastic barrel in front of an unsuspecting driver traveling at 55 mph. Of these subjects, 75 percent applied the brakes initially rather than steering. The STI study described the reaction of 17 drivers to an unexpected obstacle, where a silhouette of a vehicle was ejected into the path of a vehicle traveling 30 mph. Of the 17 drivers, seven steered around it, eight hit it, and two stopped in front of it.

Decisions That Involve Both Steering and Braking as Related to the CU Short Course. The subject vehicles are equipped with 4-wheel ABS. Vehicle manufacturers and NHTSA have told consumers with vehicles equipped with ABS to "Stomp and Steer" when they come upon an unexpected obstacle. This combination of braking and steering allows the vehicle to be slowed while turning away from or around the obstacle.

NHTSA conducted a demonstration test of the subject vehicle on the CU short course in which the driver stomped on the brakes at the same time he started to steer to the left to go around the obstacle in the left lane. The vehicle came to a stop near the entry cones on the exit gate, without any tip-up.

6.1.2 CU Short Course Testing

6.1.2.1 Subject Vehicles and Other Vehicles Tested by CU in the Summer of 1996

On the basis of tests conducted in the summer of 1996, CU reported that the 1995-96 Isuzu Trooper/Acura SLX tipped up in short course tests at speeds as low as 33 mph. After the initial series of tests (without outriggers) that resulted in tip-up, CU placed outriggers on the vehicles and made additional test runs. The highest speed reported by CU that resulted in a non-tip-up, clean run was 37.5 mph (driver KS, run 12, 7/10/96, 12:17).[10] CU observed wheel lift on this run.

CU identified many tests in which the subject vehicles tipped up. As stated earlier, CU rated these tip-ups with a severity rating (Low, Medium, and High). Of the tests in which CU videotaped the interior of the vehicle to allow analysis of steering inputs, five produced a high tip-up rating. Data from these tests and the 37.5 mph non-tip-up, clean run are shown in Table 13 (these data are from CU's November 25, 1996 submission).

Table 13. Comparisons of Selected Non Tip-up and High Tip-Up Runs Conducted by CU.

Driver	Date	Time	Speed	Left Steer	Right Steer	Total Reverse Steer	Result
KS	7/10/96	12:17	37.5	183	216	399	Fastest Non-Tip-up Clean Run [a]
EAP	6/26/96	11:15	36.6	190	320	510	High Tip Up
EAP	6/26/96	11:20	40.9	190	370	560	High Tip Up
EAP	7/10/96	13:12	37.5	191	388	579	High Tip Up
EAP	7/10/96	13:14	38.8	236	372	608	High Tip Up
ROS	8/8/96	1:59	37.9	185	365	550	High Tip Up

[a] CU stated that this was a non-tip-up run, with wheel lift.

The lowest magnitude steering inputs reported for a high tip-up run were 190 degrees left and 320 degrees right (36.6mph). This total reverse steer of 510 degrees is 111 degrees greater than the total reverse steer in the non-tip-up, clean run at a higher speed (37.5 mph). This demonstrates the effect of steering inputs on test outcome.

[10] "Short Course Summary," delivered to ODI on November 25, 1996. The steering inputs for this run were reported in the prior section.

CU used three different drivers for these tests: KS, EAP, and ROS. The CU drivers have apparently developed different strategies for driving vehicles through the short course. For example, data from the two tests that CU evaluated in its December 23, 1996 submission, are plotted in Figure 6.[11] KS (marked with squares) steered sooner than EAP (marked with dots), while EAP used more steering input than KS. The KS steering input resulted in an non-tip-up, clean run, while the EAP steering input resulted in a high tip-up, non-clean run.

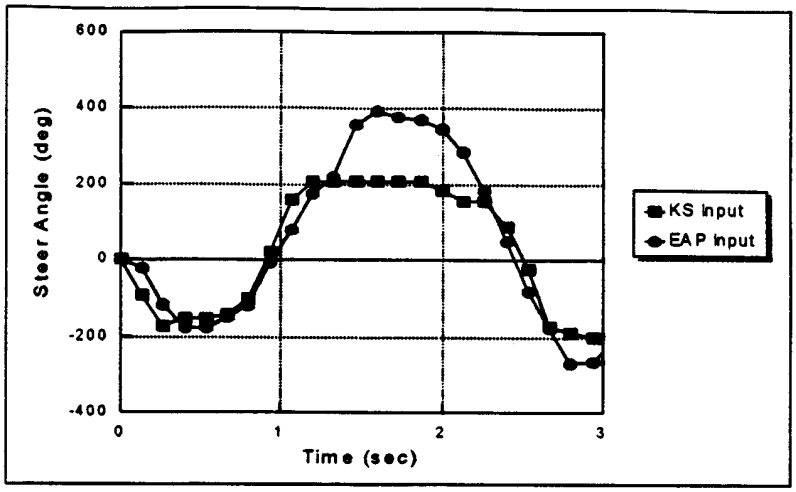

Figure 6. Clean Run Driving Profile for KS and High Tip-Up Run Driving Profile for EAP.

ODI reviewed all the test data supplied by CU for the tests in which steering inputs were reported. Each test has a maximum left and right steer associated with the first and second steering maneuvers. For each vehicle (Tahoe, Pathfinder, 4 Runner, and the subject vehicles[12]), the maximum right and left steer were averaged; i.e., for the Tahoe, the 16 tests resulted in an average left steer of 185 degrees and average right steer of 225 degrees. Table 14 presents these data.

Table 14. Average Steer Angle for CU tests on Short Course by Vehicle Tested.

Vehicle	Test Speed	Left Steer	Right Steer	Total Reverse Steer	Number of Tests
1996 Tahoe	35.2	185	225	410	16
1996 4 Runner	37.8	175	225	400	15
1996 Pathfinder	37.3	171	228	399	13
Subject Vehicles	36.6	188	312	500	124

In general, the steering inputs for the subject vehicles were greater than those for the Tahoe, Pathfinder, and 4 Runner. The three peer vehicles were driven in a very similar pattern - with the left and right inputs for each vehicle being very similar. The subject vehicles had only slightly

[11] As described in Footnote 7, because of differences in the submissions by CU, the maximum steering inputs depicted in Figure 6 are different from those included in Table 13.

[12] The subject vehicle tests included tests of three different vehicles: 1996 Trooper, 1996 SLX, and 1995 Trooper.

more left steer than the other three vehicles, but substantially more right steer – about 90 degrees more than the other vehicles.

6.1.2.2 CU Testing of the MY 1992 Isuzu Trooper in 1992

In 1992, CU conducted a series of tests to evaluate the MY 1992 Isuzu Trooper. (A new version of the Trooper had been introduced in 1992. This version continued with no relevant changes through MY 1994.) The testing included runs on the CU short course. This testing was performed by one driver, ROS, on October 28, 1992. A total of 10 runs were made; five of them were clean runs. The highest speed of the clean runs was 37.1 mph. The fastest run, conducted at a speed between 38 and 39 mph, resulted in a two-wheel lift. CU also recorded several clean runs in which one wheel lifted.

CU rated this vehicle as "Good" for "Emergency Handling."

6.1.2.3 Historical CU Testing (1988-present)

CU started using the short course in mid-1988 while evaluating the 1988 Suzuki Samurai. Since that time, CU has used it to evaluate rollover performance of 44 models (as described in issues of Consumer Reports from July 1988 through October 1996), including all SUV's and many other light vehicles, such as new entry minivans and small pickups. During that time period, CU has rated two vehicles as "Not Acceptable" in terms of rollover: the Suzuki Samurai and the subject vehicles.[13]

6.1.3 Test Results Submitted by Isuzu

6.1.3.1 Isuzu Testing

Testing in Japan
Isuzu tested the subject vehicles and the 1994 Trooper in Japan. While no documentation was submitted as to the exact course layout, it appears that the course was similar to the CU short course. The tests were documented on videotape recordings. The test vehicles were not equipped with outriggers.

This testing showed that the subject vehicles could be cleanly driven through the Isuzu version of the CU short course at speeds up to 36.6 mph, which is several mph faster than the speed at which CU reported its first two-wheel tip-up (without outriggers).

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[13] Three of the vehicles that CU did not find to be "Not Acceptable" had tip-ups in CU tests on the short course: the 1989 Ford Bronco II, the 1992 Mitsubishi Montero, and the 1992 Isuzu Trooper.

Isuzu's testing of the 1994 Trooper indicated that its performance on the Isuzu version of the CU short course was similar to that of the subject vehicles. Isuzu conducted several clean runs with this vehicle, at speeds up to 36.5 mph.

Other Isuzu Test Information
Isuzu also submitted a compilation of historical testing (conducted by several organizations) which purported to show that many vehicles could be made to tip up on dry roadway surfaces. Several maneuvers were used, including crash avoidance and J-turns.[14]

6.1.3.2 Carr Testing

Isuzu also submitted tests of a 1996 Trooper conducted by Carr Engineering using the CU short course, without outriggers. Typical test speeds ranged between 30 and 37 mph. The vehicle was instrumented to collect steering inputs, as well as an assortment of vehicle dynamic data, including lateral acceleration. The fastest clean run by Carr was at 36 mph (Carr Test 34). The steering inputs on this run were 175 degrees to the left and 235 degrees to the right; thus, the total reverse steer was 410 degrees. These steering inputs were similar to those on the clean run that CU driver KS had at 37.5 mph.

6.1.4 NHTSA Testing

Tests were conducted by NHTSA in two locations: the Vehicle Dynamics Area (VDA) at TRC, which is a 50-acre asphalt pad, and an asphalt runway at the UTQG test facility.

Initial testing conducted at TRC was based on an improperly labeled drawing of the CU short course.[15] The centers of the entrance lane cones were nine feet apart, while the inside bases of the left and right side cones should have been eight feet apart. In addition, the right gate cone was centered three feet into the second lane, while the inside base of that cone should have been three feet into the lane. A comparison of the CU short course and the course originally used at TRC is

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[14] The steering inputs made by the drivers in these tests were not reported.

[15] In its October 10, 1996 submission, CU supplied a drawing that reflected the layout of the CU short course. This drawing did not give the exact cone placement to mark the lane widths or offset gate placement. At Isuzu's press conference (September 12, 1996), Isuzu presented an analysis conducted by Carr Engineering that purported to depict the CU short course in detail. NHTSA used the Carr drawing of the course during its initial round of testing at TRC. In its December 23, 1996 submission, CU submitted a higher quality drawing of the CU short course, shown earlier in this section. At this point NHTSA realized the original course was not precisely identical to the CU short course and changed the course accordingly. All tests conducted in Texas and those conducted in Ohio after the Texas testing (except for the evaluation tests to compare the two courses and to ascertain the effect of outriggers) were on a course identical to that used by CU.

given in Figure 7. Since the original TRC course was set up on cone centers, the diameter of the cones affect the inside base distances. The cone size used in this TRC testing resulted in an inside base distance of eight feet six inches, as compared to the CU short course distance of eight feet, and an inside base gate cone distance of three feet three inches, as compared to the CU short course distance of three feet.[16] All short course testing at the UTQG facility was on a course identical to the CU short course.

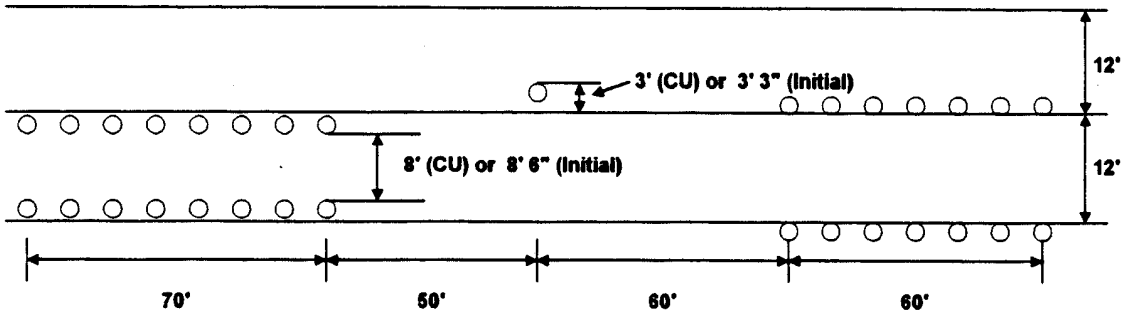

Figure 7. Differences between CU Short Course and Initial TRC Course.

Phase 1 Testing in Ohio

The following vehicle configurations were tested at TRC on the initial course layout, using Bridgestone Dueler tires.

1996 Acura SLX without outriggers
1996 Acura SLX with VRTC outriggers

Testing was first performed without outriggers at speeds from 26 to 32 mph. There was no sign of wheel lift. VRTC outriggers were then added to the vehicle, and the vehicle was tested at nominal[17] speeds ranging from 30 to 40 mph. In general, the tests up to a nominal speed of 38 mph produced very little or no front wheel lift. The highest actual test speed that produced a clean run was 37.6 mph.

[16] NHTSA has compared the results of the tests conducted on the initial TRC layout with those conducted at TRC using the precise CU course layout. These results indicate that the slight differences in the cone placement did not produce significantly different results. For example, the maximum clean run speeds for both courses were very similar (37.6 mph in Test 76 and 37.3 mph for Test 559). See Appendix E of the VRTC report for more details.

[17] The term "nominal speed" indicates the target speed for a set of runs. Typically, tests were conducted with a target speed in two mph increments; i.e., 30, 32, 34 mph, etc. The actual test speed was collected with on-board instrumentation.

At 40 mph, front wheel lift was more noticeable, and there was one test that produced significant tip-up; the outrigger hit the ground. Another test produced significant front wheel lift, but the vehicle did not approach a rollover.

These results did not coincide with the lower tip-up speeds reported by CU, so several tests were run to try to produce a tip-up at lower speeds using an Acura SLX with VRTC outriggers. The methodology used to intentionally tip the vehicle (characterized by the test driver as "whipping" the steering wheel) was to increase the steer angle and steer rate, especially for the reverse steer. The initial steer was also slightly delayed.

Intentional tip-ups were produced at speeds as low as 35.2 mph. Attempts to tip the vehicle up at 34 mph were unsuccessful. The left and right maximum steer angles and total reverse steer angles for two clean runs and two intentional tip-up runs at nominal speeds of 36 mph are given in Table 15.

Table 15. Comparison of VRTC Tests, Showing Test Speed, Steer Angles, and Steer Rates for Clean and Intentional Tip-Up Runs - Acura SLX, with VRTC Outriggers.

Test Outcome	Speed (mph)	Left Steer (deg)	Left Steer Rate (deg/sec)	Right Steer (deg)	Right Steer Rate (deg/sec)	Total Steer (deg)	VRTC Test Reference Number
Clean Run [a]	36.5	202	891	236	1053	438	55
Clean Run [a]	36.0	210	1030	258	1007	468	57
Tip-Up Run [b]	36.6	225	832	332	1389	557	106
Tip-Up Run [b]	35.2	228	875	395	1383	623	109

[a] These runs did not have a tip-up.
[b] These runs were not clean.

These data indicate that while testing at the same nominal speed, dramatic differences in the outcome can be generated by the test driver. A slight increase in the left steer with similar steering rates, followed by a substantial increase in the right steer at a much higher rate produced tip-up, while the vehicle could go through the course successfully with less severe steering inputs.

Testing in Texas

Due to inclement weather in Ohio, NHTSA's testing was continued at the UTQG facility in San Angelo, Texas. The following vehicle configurations were tested at this site:

1996 Isuzu Trooper (CU) with CU outriggers and Goodyear Wrangler Tires
1996 Isuzu Trooper (CU) with CU outriggers and Bridgestone Dueler Tires
1996 Acura SLX with VRTC outriggers and Bridgestone Dueler Tires
1994 Isuzu Trooper with VRTC outriggers and Bridgestone Dueler Tires

The primary purpose of these tests was to compare the performance of the subject vehicles with that of the 1994 Trooper.

Subject Vehicle Testing in Texas

At no time did tip-up occur at nominal speeds less than 38 mph, so this summary will concentrate on the tests at 38 mph. Out of 49 tests with the subject vehicles (33 with the 1996 Trooper and 16 with the 1996 SLX) at this speed, there were two significant tip-ups, each with the 1996 Trooper equipped with the CU outriggers and Bridgestone Dueler tires.

These results suggest that the Bridgestone Dueler tires were slightly more aggressive (as reflected by their ability to produce a tip-up for the 1996 Trooper) than the Goodyear Wranglers. However, these data cannot be the basis for definitive findings about tire aggressivity due to possible variations in the test surface and the lack of repeatability of the driver inputs.

The 1996 Acura SLX with VRTC outriggers produced no tip-ups at 38 mph.

Peer Vehicle (1994 Trooper) Testing in Texas

Prior to beginning NHTSA's tests of the 1994 Trooper, it was observed that the test surface had become heavily covered with black marks, most likely from tire wear, but possibly from tar coming out of the test surface. Because of a concern that the surface might have changed, a second, "new" surface was set up. To accomplish this, the course direction was reversed; i.e., the twelve-foot wide exit lane became an eight-foot wide entrance lane and vice versa. This reversal had the effect of placing the area in which the vehicle was turned on relatively clean pavement. The "new" course was first used with the 1996 Trooper with the Bridgestone tires.

Out of 24 tests conducted with the 1994 Trooper at a nominal speed of 38 mph, 19 were run on the "old" course and five were run on the "new" course. There were two tip-ups on the "new" course and no tip-ups on the "old" course. Since no tip-ups occurred when the 1994 Trooper was tested on the "old" course, even though there were greater steering inputs on some test runs, it was theorized that previous testing on the "old" course had affected the friction properties of the test surface. It was later confirmed that the original course had a significantly lower skid number[18] than the new course, even after a few tests had been conducted.[19]

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[18] Skid Number refers to the frictional resistance of the pavement measured in accordance with ASTM E-274. Higher skid numbers mean that the pavement has a higher frictional resistance. As the skid number of a surface decreases, a vehicle's ability to generate lateral traction diminishes. This would generally lower the maximum speed at which a vehicle could be driven through the course cleanly. A lower skid number surface would also diminish the likelihood of rollover, since the lower pavement resistance would be insufficient to generate the needed forces at the tire/road interface to cause rollover. This principle is demonstrated by the fact that it is very difficult to roll a vehicle on an icy road surface.

[19] See VRTC test report; Appendix F for more details.

The peer vehicle testing was compared to the subject vehicle testing to ascertain whether the tests were conducted in a similar manner. Table 16 presents the average speed and left and right steering inputs for these tests. As these data indicate, the tests were conducted in a similar manner.

Table 16. Comparison of Subject Vehicle and Peer Vehicle Test Speeds and Steering Inputs for Tests at a Nominal Speed of 38 mph.

Vehicle	Number of Tests	Average Speed (mph)	Average Left Steer Input (deg)	Average Left Steer Rate (deg/sec)	Average Right Steer Input (deg)	Average Right Steer Rate (deg/sec)	Total Reverse Steer (deg)
Subject Vehicles	49	38.4	215	852	265	1113	480
Peer Vehicles	24	38.6	225	921	258	1144	483

Phase 2 Testing in Ohio

NHTSA conducted a second phase of tests at TRC after completion of the testing in Texas. These included 122 tests to investigate two issues: 1) the effects of outriggers on a vehicle's performance on the CU short course; and 2) whether differences between the initial TRC course (used during the beginning of NHTSA's test program) and the course used in Texas (a course setup precisely like the CU course) resulted in differences in vehicle performance.

The results of the outrigger-effect testing will be discussed in Section 6.4, while the effect of the differences in the two courses was discussed at the beginning of this section.

6.2 Suzuki Testing

Suzuki submitted test results for many vehicles which it had tested on a course similar to the CU short course. This testing demonstrated that many vehicles could be tipped onto two wheels. Suzuki did not test the subject vehicles.

6.3 Understeer/Oversteer [20]

Based on analysis using a simulation model (discussed in Section 7, below), CU claimed that the subject vehicle will oversteer at high lateral acceleration levels.[21] CU's analysis was based on computer simulation of a vehicle's behavior while slowly increasing its speed around a constant radius turn, rather than using the CU short course. Both Isuzu and NHTSA conducted tests to ascertain whether this actually occurred at high lateral acceleration levels (in the 0.65 to 0.75 g range).[22] A vehicle which changes from understeer to oversteer at high lateral acceleration levels would generate higher sideslip angles. These high sideslip angles could generate more lateral force acting through the vehicle's center of gravity, which would make the vehicle more likely to tip over.

6.3.1 Isuzu Testing

Isuzu's April 8, 1997 submission presented a series of tests to determine the subject vehicles' propensity to understeer or oversteer under certain circumstances. Data were derived from a series of tests around a constant-radius path, at an ever-increasing speed. The faster speeds require more steering wheel angle to maintain a constant-radius path, which in turn generates higher lateral accelerations. Isuzu used the relationship between the steering wheel angle and the measured lateral g's to determine understeer/oversteer. Isuzu claims that "... one can see that the vehicle is definitely understeering and that it tends to plow out at the limit."

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[20] A vehicle is said to understeer when, as lateral acceleration increases, the slip angle at the front axle increases more than it does at the rear axle. The opposite applies for a vehicle which oversteers. In layman's terms, an understeer vehicle "plows out" – that is, tends to go straighter than expected -- while an oversteer vehicle "spins out" – that is, the rear end tends to swing around. A vehicle that oversteers has more sideslip and yaw angle during a turning maneuver, which generates more lateral force. Increased lateral force will develop additional roll (lean) in the vehicle and could generate sufficient forces to roll the vehicle over.

[21] Lateral accelerations are generated while driving a vehicle through different maneuvers. Suzuki submitted data that indicates that typical driving on freeways generate lateral accelerations of up to about 0.16 g's; surface streets generate up to about 0.25 g's; emergency turns generate up to about 0.45 g's; and the ISO lane change maneuver generates up to about 0.48 g's. Reference: Suzuki letter dated March 19, 1997, Attachment A, Figure 4.1.

[22] NHTSA considered possible methods to measure vehicle understeer/oversteer during the transient maneuver associated with the steering reversal (right turn) in the CU short course. However, the agency was unable to identify any practicable methods to obtain such measurements. Based on the facts that NHTSA could not identify a practicable method to measure oversteer in the reverse steer maneuver and since CU used a standard industry approach to determine understeer/oversteer, NHTSA used an approach similar to CU's; that is, it measured the vehicle's response to a series of increasing steering inputs in a single direction.

6.3.2 NHTSA Testing

NHTSA conducted a series of step- steer tests using a committee draft of International Standards Organization (ISO) 7401 procedure "Road Vehicles - Lateral Transient Response Test Methods Part 1: Fixed Steer Control."[23] NHTSA used the 1996 Acura SLX without outriggers. During step-steer testing, the steering wheel is set up in a way that it can be turned to a preset steer angle, which is referred to as a "step." The step is increased on each run until all desired steer angles are tested. On each run, the driver turns the steering wheel as fast as possible to the steering stop and holds it there until the vehicle reaches a steady-state condition, holding the throttle constant and without applying the brakes.

Testing was conducted at 40 mph to steer angles of 230 degrees, which resulted in lateral acceleration levels of nearly 0.8 g, a very high lateral acceleration. The results of these tests are plotted in Figure 8. These data indicate that the vehicle exhibits understeer throughout the range of testing; that is, for each percentage increase in the steering wheel angle, there is an even smaller percentage increase in lateral acceleration.

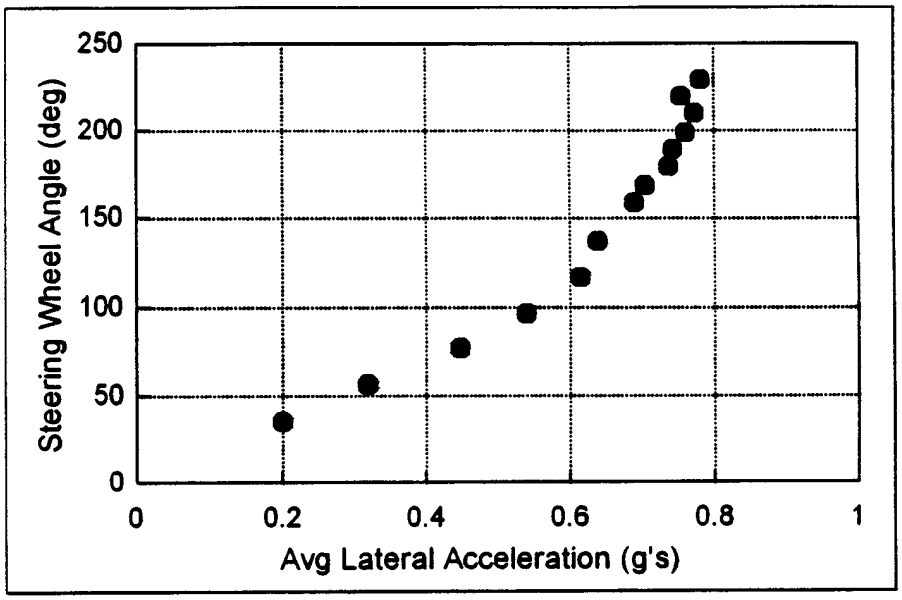

Figure 8. Steering Wheel Angle vs. Lateral Acceleration, 40 mph, 1996 Acura SLX w/o Outriggers.

6.4 Outrigger Effects On Test Outcome

Since Isuzu's tests of the subject vehicles without outriggers did not lead to tip-ups, and since the 1996 Isuzu Trooper with CU outriggers seemed to more readily tip up than the 1996 Acura SLX

[23] There are two primary methods for determining the relationship between steer angle and lateral acceleration. One is to drive around a constant radius curve at an increasingly faster speed. Each speed increment will require additional steering angle to maintain the path. (This is the method used by Isuzu that was described in the prior section.) Another method, which can only be used with a large test area, is to conduct all the tests at the same speed. Using this method, the steer angle is increased in steps, and the resultant lateral acceleration is measured. Since the CU tests were conducted at speeds around 40 mph, NHTSA used the step-steer test to measure the steer angle-lateral acceleration relationship at that speed.

with VRTC outriggers at similar test speeds, NHTSA attempted to ascertain the effects of the outriggers on tip-up propensity. Tests were run on the CU short course with the 1996 Acura SLX with no outriggers, VRTC outriggers, and CU outriggers.[24] The no-outrigger tests were run at a nominal speed of 34 mph, while those with the outriggers were run at nominal speeds of 34, 36 and 38 mph.

The vehicle was driven by a test driver, so the steering inputs for each test configuration could not be repeated exactly, but enough tests were run to allow a comparison of vehicle responses. For the lower levels of initial steer (200-210 degree range), the driver needed to put in significantly more second steer for the VRTC-outrigger configuration than for the no-outrigger configuration. At higher levels of initial steer (210-230 degree range), the second steer for the VRTC-outrigger configuration was only slightly greater. The first and the second steer inputs were significantly greater for the CU-outrigger configuration than for both the no-outrigger and the VRTC-outrigger configurations. The details of this testing are discussed in the VRTC report.

7.0 SIMULATION RESULTS

Computer simulation is a tool used by many researchers to investigate the dynamic performance of vehicles. In the mid 1980's, NHTSA entered into a contract with STI to develop a vehicle handling computer simulation program. The result of that effort was the computer simulation Vehicle Dynamics Analysis, Non-Linear (VDANL). VDANL has been upgraded over the years to expand and improve its capabilities. This simulation program has been utilized by CU and Isuzu to analyze the subject vehicle's performance in certain crash avoidance maneuvers.

Simulations are generally validated through actual field testing by comparing the field observations to those predicted by the simulation. When agreement is achieved for a particular test or maneuver (based on a comparison of various attributes from the model and test, such as path position, angular and linear rates and accelerations, etc.), the model is considered validated with respect to that test or maneuver. The zone of agreement between the actual test results and the computer simulation is referred to as the range of validation.

Often the simulation's predictions are good for some period, but degrade as the simulation continues. For example, a simulation may predict well during the beginning of the modeled event, but degrade with time.

A simulation may also be validated for maneuvers that regularly occur in normal driving, but not give predictive results for maneuvers that are near or at the limit of a vehicle's performance envelope. In these extreme cases, the accuracy of the input data that describe the vehicle's

[24] The VRTC outriggers, which are installed near the vehicle's fore-aft cg, are made of steel and aluminum, use small casters for wheels, and weigh about 115 lbs. The CU outriggers, which are installed at the vehicle's front and rear, are made of steel pipe, use trailer wheels, and add about 270 lbs to the vehicle's weight (the bumper is removed for installation).

attributes becomes particularly important. Typically, these attributes, such as spring rates, tire factors, inertial factors, etc., need to be measured with extreme precision to obtain the best results. However, as a practical matter, it may not be possible to obtain exact measurements, and estimates are often used. When these estimates are not precisely accurate, there may not be agreement between the computer simulation prediction and actual vehicle performance, especially during severe maneuvers. When this occurs, the simulation is considered to be not validated under these circumstances and cannot legitimately be used to predict vehicle performance during those maneuvers.

7.1 Petitioner's Simulations

CU submitted two experts' reports with its December 23, 1996 submission. These reports were authored by Ian Jones of Ian S. Jones & Associates and Wade Allen of STI. Both Jones and Allen used parametric data for the subject vehicles obtained from S.E.A., Inc. and Calspan.

7.1.1 Jones Simulation

Jones reported that using the VDANL simulation program, he was able to independently confirm that the subject vehicles will tip up during the CU short course maneuver. Jones cited an independent evaluation of VDANL by the Iowa State University, which concluded that VDANL most closely modeled vehicles at their limit of performance.

Jones also analyzed several potential improvements to the subject vehicles, including increasing the front roll stiffness, lowering the cg, and changing the track width. Jones asserted that increasing the front roll stiffness would improve the vehicles' ability to proceed through the CU short course without tip-up.

7.1.2 Allen Simulation

Allen conducted VDANL simulations using two maneuvers: steady state and steering reversal. Parametric inputs for the simulations were the same as those used by Jones.

Allen computed understeer/oversteer for the subject vehicles. For lateral acceleration levels up to about 0.65 g's, Allen's analysis showed the vehicle would understeer. For higher lateral acceleration levels (above 0.65 g's), the simulation indicated the vehicle would oversteer. Allen concluded that the vehicle needs additional roll stiffness in the front axle to avoid oversteering at high lateral accelerations.

Allen also reported that the simulation predicted that the vehicle would roll over in a steering-reversal maneuver.[25] Simulation results were presented to support this finding.

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[25] The steering wheel input simulated by Allen was trapezoidal in nature, consisting of a right steer to 3.0 radians (172 degrees) in 0.25 seconds, which is held for 0.25 seconds (0.5

Allen suggested that increasing the size of the front anti-roll bar would make the subject vehicle more stable and less prone to roll over during a reverse-steer maneuver. Using the VDANL program, Allen presented simulation data to demonstrate improved rollover performance with the proposed "remedy."

7.2 Isuzu's Simulation

Isuzu contracted with S.E.A., Inc., the same company that had measured the subject vehicle's parameters for the petitioner, to assess the validity of VDANL for use in limit maneuvers, such as a rollover event. This work was performed by Gary Heydinger.

Heydinger found several problems with the VDANL simulation program in the context of the issues raised by this petition. He concluded that VDANL did not accurately model the performance of the subject vehicles at a limit condition, primarily due to a shortcoming in its suspension sub-program. The suspension sub-program is a portion of the simulation program that simulates what will occur when the forces acting on the vehicle's sprung mass are transmitted through the load paths to the axles, wheels, tires, and finally to the road.

The suspension of the subject vehicles is comprised of several components, including the springs and dampers. The spring system consists of the main springs (torsion bars in the front and coil in the rear), stabilizer bars (front and rear), and bump stops (front and rear). The dampers consist of friction in the suspension joints and the shock absorbers (front and rear).

Heydinger concluded that the vehicle's bump stops, the portion of the suspension which is contacted when the springs reach either their maximum or minimum extension,[26] were not modeled correctly in the VDANL simulations performed by Jones and Allen. These devices are often contacted when the vehicle leans while making a very hard turn, and they control the amount of lean during some limit maneuvers, such as a severe steering reversal. As the vehicle leans, one side of the suspension compresses and the other side extends, both front and rear. In a severe turn, this can continue until the vehicle's suspension reaches bump stop engagement.

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seconds of accumulated time), followed by a left steer to -3.0 radians (-172 degrees) in the next 0.5 seconds (1.0 seconds of accumulated time). This steering wheel angle is held for the remainder of the simulation. This input is somewhat like the CU short course, except the timing is fixed and the steering wheel is not returned to center after the second steer.

[26] For example, minimum extension bump stops are the devices that are hit when a driver "bottoms out" a car's suspension, such as when going over a deep pot hole. Maximum stops are the devices which limit the extension travel of the vehicle's springs, and are often incorporated into the vehicle's shock absorbers as a limiting device that is engaged when the shock absorber reaches its full extension.

The VDANL program does not include data reflecting the actual bump stops in the subject vehicles. Rather, the simulation uses a generic bump stop model. According to Heydinger, the shortcomings of this bump stop model include: 1) single value stiffness in bounce and rebound, 2) same value of stiffness front and rear, 3) suspension travel to engagement is the same in bounce and rebound, and 4) suspension travel to engagement is the same front and rear. Heydinger concluded that "the modeling of the bump stops and lack of modeling nonlinear suspension characteristics is inadequate for correctly modeling suspension behavior ... at high lateral acceleration levels." Heydinger presented simulation runs where the bump stop forces were graphically shown. It could be seen that the bump stop forces were significant. This suggests that the correct modeling of these items could be important in predicting the performance of the subject vehicles during maneuvers in which the bump stops are engaged, such as severe crash avoidance maneuvers. In the subject vehicles, the bump stops are engaged at about five to six degrees of roll angle, considerably less than the roll angle experienced by the subject vehicle in the CU short course.

8.0 CRASH DATA

The National Automotive Sampling System (NASS) data were analyzed to determine the type of vehicle maneuver that is associated with an on-road or on-shoulder rollover crash. FARS data were also reviewed. Suzuki submitted an analysis of crash data. Isuzu and CU did not supply any crash data.

8.1 NASS Data Analysis

ODI reviewed the 1992-1995 NASS data files. During this four-year period, weighted[27] estimates from NASS data indicate that there were 11,244,450 tow-away crashes. Of these, 779,502 were rollover crashes. Of these rollovers, 337,307 were first-event, single-vehicle rollovers.

ODI conducted a more detailed (hard copy) analysis of first-event, single-vehicle rollovers in the NASS files that occurred on the roadway or shoulder. Crashes that were coded as having been caused by a vehicle problem, e.g., tire, engine, etc., were excluded, although rollovers that were related to the vehicle's operation, such as overloaded vehicle, high cg of truck-mounted equipment, wheel shimmy, and brake grab causing loss of control, were kept in the analysis. Also, crashes in which the vehicle that rolled over was towing another unit were excluded. Using these criteria, 60 individual cases were identified, which represent 23,247 single-vehicle rollover crashes occurring on the road or shoulder. The 60 cases can be grouped into several general categories, as shown in Table 17.

[27] Weighted values in NASS are determined through statistical sampling techniques. They allow the use of the NASS sample of about 5,000 to 6,000 annual cases to produce estimates representative of the annual total of tow-away crashes on our nation's highways.

Table 17. On-Road/Shoulder First-Event Rollovers from NASS, by Crash Type, 1992-1995.			
Category	**Number of Rollover Cases**	**Weighted Value of Rollover Cases [28]**	**Standard Error [a] (crashes)**
Operational Related	6	3,919	± 3,416
Run off the road	24	2,866	± 1,181
Crash Avoidance	12	12,053	± 6,849
Road Conditions	8	2,620	± 1,968
Excessive Speed	4	842	± 757
Lost Control	6	947	± 527
Totals	60	23,247	± 8,839
[a] - Standard Errors were determined using SUDAAN.			

Using NASS weighted values for these four years, there were 12,053 rollovers that occurred on the road or shoulder that involved a crash avoidance maneuver. This represents, during the time period, 0.11 ± 0.06 percent of all crashes, 1.55 ± 0.88 percent of all rollover crashes, and 3.56 ± 2.04 percent of all first-event, single-vehicle rollover crashes.

8.2 FARS and State Crash Data

Since the subject vehicles are very new, MY 1995-96, and since crash data tends to be delayed one to two years, there were insufficient crash data to allow ODI to compare the real-world rollover performance of the subject vehicles with that of their peers. Review of the FARS data indicate that there have been no rollover crashes with the subject vehicles, and therefore no evidence from FARS that indicate the subject vehicles are worse that their peers. An analysis of crash data from five states found very minimal crash exposure for the subject vehicles, hence no statistically valid comparative analyses could be performed.

8.3 Suzuki Data

Suzuki submitted several crash data analyses. One analysis used FARS data to estimate the frequency of first-event rollovers on the roadway in single-vehicle crashes involving an avoidance maneuver, defined as a crash in which the vehicle overturned without first leaving the roadway. Suzuki claims that this analysis assesses the representativeness of the CU's procedure in testing the rollover propensity of light trucks in crash avoidance maneuvers. The analysis finds that only 0.4 percent of the 58,366 light trucks in fatal single-vehicle crashes in FARS between 1982 and

[28] These figures have been adjusted to account for cases in the NASS data file where the selection variables were coded as "unknown" (about 1,750 crashes).

1995 fit the above criteria. Using the variable "Crash Avoidance Maneuver" introduced in FARS in 1991, the authors present a similar calculation for crash-involved sport utility vehicles with an occupant fatality. They find that between 1991 and 1995, out of 4,494 such cases in FARS, only 0.1 percent were single-vehicle, first-event rollovers on the roadway taking place while maneuvering to avoid a vehicle, pedestrian, or other object on two-lane undivided road with a speed limit of 45 mph or less and involving steering-only maneuvers.

Suzuki also presented an analysis of North Carolina state data for 1979-1995, which indicates that out of 169,441 light trucks in single-vehicle crashes, only 0.6 percent were first-event, single vehicle rollovers without leaving the roadway with an avoidance maneuver. Using the North Carolina data for 1982-1995, the authors also found that out of 66,584 crashes involving sport utility vehicles, only 0.005 percent were first-event, single-vehicle rollovers taking place while maneuvering to avoid a vehicle, pedestrian, or other object on a two-lane undivided road with a speed limit of 45 mph or lower.

The statistical validity of Suzuki's analyses is questionable because they do not address the problem of missing data (which affects a large portion of the data elements used), and the interpretation of the variables "Vehicle Maneuver," and "Crash Avoidance Maneuver" is not clear (they seem to be interpreted as overlapping). Also, the criteria chosen to classify crashes as relevant to the CU test are too narrow. The additional requirement that the road be a two-lane highway with speed limit of 45 mph or less is even more restrictive. For these reasons, ODI did not rely upon these Suzuki analyses in deciding whether to grant or deny the petition.

Suzuki also presented a multi-state analysis, comparing the rollover rates (rollovers per single-vehicle crash and rollovers per registered vehicle) for many 4x4 SUV's with the vehicles' CU "Emergency Handling" rating; i.e., Poor through Excellent. However, CU did not claim that its "Emergency Handling" rating would correlate with rollover propensity. Rather, CU's determination as to whether a vehicle's rollover performance is "Not Acceptable" is based solely on its performance on the short course, and the short course tests are not utilized by CU in developing its "Emergency Handling" rating. Hence, Suzuki's effort to demonstrate that there is no correlation between CU's "Emergency Handling" ratings and the vehicles' rollover rate is not relevant to this petition analysis.

9.0 FINDINGS

① A comparison of the vehicle parameters of the subject vehicles with those of the 1992-1994 Trooper does not provide any basis on which to conclude that the subject vehicles have a greater rollover propensity. In fact, the subject vehicles have a wider wheel base, higher static stability factor, and higher tilt table ratio, which, if all other things were equal, would suggest that they are less likely to roll over.

② Analyses of rollover complaints in the ODI consumer data base data do not suggest that the subject vehicles have an abnormally high rollover propensity. Analysis of FARS and state data bases indicate that there are insufficient data to conduct a statistically valid comparative analysis.

③ Although the VDANL simulation program provides valid predictions of vehicle behavior during most vehicle operations, a shortcoming in its suspension sub-program undermines its ability to predict the precise performance of the subject vehicles at certain limit conditions, such as those experienced during the CU short course maneuver and other severe driving maneuvers that cause the vehicles' bump stops to be engaged.

④ Although the computer simulation submitted by CU indicated that the subject vehicles would switch from understeer to oversteer at high lateral acceleration levels, testing of the subject vehicles by NHTSA and Isuzu indicates that the vehicles understeer throughout a range of lateral accelerations up to nearly 0.8 g's.

⑤ ODI's review of tests performed by CU drivers on the CU short course demonstrates that the test can be and has been conducted with a variety of strategies, including timing of turns, severity of steering inputs, and rate of steering inputs, which can lead to different results under similar initial conditions.

⑥ In testing conducted by NHTSA on the CU short course, the results of tests of a peer vehicle (the 1994 Trooper) were similar to those of the subject vehicles.

⑦ Equipping a vehicle with outriggers has an effect on the vehicle's performance on the CU short course. These effects are more noticeable with the CU outriggers than with the lighter VRTC outriggers.

⑧ Data developed during ODI's testing and its review of the CU tests, demonstrates that the CU short course test, as conducted by CU, does not provide a sufficient scientific basis on which to determine the existence of a safety-related defect.

10.0 CONCLUSIONS

Because of deficiencies in the CU short course testing and since none of the other information reviewed by ODI indicates that a safety-related defect exists, there is no reasonable possibility that an order concerning the notification and remedy of a safety-related defect in the subject vehicles would be issued at the conclusion of an investigation.

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Part IV

Department of Housing and Urban Development

Department of Health and Human Services

Notice of Funding Availability Community Partnerships for Resident Uplift and Economic Development; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FR–4240–N–01]

Notice of Funding Availability Community Partnerships for Resident Uplift and Economic Development

AGENCIES: Sponsors of this interagency public/private competitive grant announcement are:

(a) Department of Housing and Urban Development (HUD):

(1) Office of the Assistant Secretary for Public and Indian Housing, Office of Community Relations and Involvement (OCRI);

(2) Office of the Assistant Secretary for Community Planning and Development, Empowerment Zones and Enterprise Communities (EZ/EC);

(b) Department of Health and Human Services (HHS):

(1) Administration for Children and Families, Office of Community Services (OCS);

(2) Administration for Children and Families, Office of Family Assistance (OFA);

(3) Administration for Children and Families, Child Care Bureau (CCB);

(4) Office of Intergovernmental Affairs;

(c) Department of Agriculture (USDA):

(1) Cooperative State Research, Education, and Extension Service; and

(d) Boys & Girls Clubs of America (B&GCA).

ACTION: Notice of Funding Availability (NOFA).

SUMMARY: Several Federal and private agencies are combining over $6 million dollars in program funds and technical assistance in a consolidated competitive grant initiative entitled Community Partnerships for Resident Uplift and Economic Development. The purpose of this initiative is to create neighborhood-based programs to move families residing in public housing and the adjacent neighborhood from welfare to self-sufficiency. To accomplish this, the sponsors are pursuing and linking two (2) primary strategies:

(1) Encourage the creation of employment and business development opportunities for low-income people through business, physical or commercial development in the neighborhood; and

(2) Provide an array of supportive services in neighborhood-based comprehensive service centers (and accessible to persons with disabilities) to enable participants to successfully make and sustain the transition to self-sufficiency.

Approximately seven (7) urban, suburban and rural communities of varying sizes will be selected.

The sponsors of this initiative are three (3) separate Federal departments, specifically HUD, HHS, and USDA, as well as a major national private sector organization, the Boys & Girls Club of America (please see the above list under the heading **AGENCIES:**). They are coordinating several existing programs in one integrated solicitation. It is important to understand that this is a coordinated grant, not a block grant.

Although there is only one grant announcement (this NOFA) and a single application package for funding under this initiative, each sponsoring agency will award and administer the grants through a coordinating committee composed of program managers from each of the agencies (the Interagency Agreement reflects this arrangement). Co-applicants could receive up to two Federal grant awards (HUD and HHS) and additional funding from the Boys & Girls Club of America for this collaborative project.

The structure of the initiative reflects this collaborative approach. Specifically, at a minimum, there must be two co-applicants: a public housing authority and a community development corporation. There may be other co-applicants. Co-applicants carry legal responsibility for the performance of the grant. The co-applicants must develop partnerships with the residents, one or more local businesses, and the State Welfare and Child Care departments in order to be considered for this grant.

An important feature of this initiative is its short duration and ambitious agenda. The initiative, therefore, is geared to housing authority communities which already have in place operational components such as needs assessments and economic development incentive packages. The intent of this initiative is to integrate existing resources and focus them on families affected by welfare reform to achieve the specific outcome of self-sufficiency.

Application Deadline Dates: HUD will serve as the receiving agency for applications on behalf of all the co-sponsors.

(a) Applications for funding under this NOFA must be physically received at the correct HUD Headquarters Office on or before September 12, 1997 at 3:00 pm, local time. This application deadline is firm as to date and hour.

(b) In the interest of fairness to all competing co-applicants, the Departments will treat as ineligible for consideration any application that is received after the respective program deadline. Co-applicants should take this practice into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by any unanticipated or delivery-related problems. Delivery of applications by facsimile (FAX) is not acceptable.

Application Submission Requirements: The Community Partnerships for Resident Uplift and Economic Development NOFA is required as the formal submission to apply for funding under this initiative. The application checklist in Appendix A contains information on all exhibits and certifications required under this NOFA, as well as additional guidance. An application package consists of one application per each co-applicant. Only one application from each co-applicant may be submitted under this initiative (See Appendix A for each co-applicant's submission within the consolidated application package). The NOFA may be obtained from the HUD Resident Initiatives Clearinghouse, telephone 1–800–955–2232.

An original application and two identical copies of the original application must be received by the deadline at the following address. It is not sufficient for an application to bear a postage date within the submission time period. Applications should be addressed to: Patricia Arnaudo, Senior Program Advisor, U.S. Department of Housing and Urban Development, Office of Community Relations and Involvement, 451 Seventh Street, SW, Room 4126, Washington, DC 20410–5000. Applications may also be addressed to La Wanda Young, Administrative Officer, at the same address.

Program Information Contacts: For questions concerning the Department of Housing and Urban Development (HUD), contact Patricia Arnaudo, Office of Community Relations and Involvement, 451 7th Street SW Washington DC 20410, telephone (202) 619–8201 ext. 4250 or call HUD's Resident Initiatives Clearinghouse, telephone (800) 955–2232; or consult the funding cross reference under HUD's Business and Community Partner HomePage on the Internet's World Wide Web (http://www.hud.gov/bushome.html): look under funding, then under Public Housing, and then under OCRI.

For questions concerning the U.S. Department of Health and Human Services, contact Thelma Woodland, HHS Administration for Children and

Families, 370 L'Enfant Promenade S.W., Washington D.C. 20447, telephone (202) 401–5294, fax (202) 401–4687, e-mail: twoodland@acf.dhhs.gov.

Hearing-or-speech impaired persons may call (800) 877–8339. (Federal Information Relay Service TTY.) Except for the ''800'' number, these telephone numbers are not toll-free.

SUPPLEMENTARY INFORMATION:

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Part I—Summary and Overview

(a) Background

The recent passage of The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104–73) transformed the former Aid to Families with Dependent Children (AFDC) program into the Temporary Assistance to Needy Families Program (TANF). This change confronts the public housing and surrounding communities with a profound challenge and opportunity. The role of the Federal government changed from manager of the welfare system to a partner with the states in identifying how best to assist recipients to effect their transition from welfare to work. As a result, it is important that the combined funding of a variety of discretionary programs from the sponsoring Federal Departments be used to encourage local partnerships and innovation in utilizing public and private resources to address complex problems with the corresponding multiple strategies as contained in this initiative. This specifically entails the simultaneous implementation of accessible human services centers, economic development, and job creation with the primary focus on individual economic self-sufficiency.

Approximately forty percent (40%) of the families residing in public housing list AFDC/TANF as their primary source of income. The rewards of moving this substantial segment of the public housing residents from welfare dependency to work and self sufficiency have never been more clear. The potential consequences of failure are equally clear and threaten not only the economic well being of individual families, but of entire public housing neighborhoods that could experience significant losses of rental income as residents become ineligible for further welfare assistance.

(b) Purpose

(1) This initiative is designed to assist public housing residents and others in the surrounding neighborhood who are affected by welfare reform in becoming economically self-sufficient. The co-sponsors believe that an effective joint welfare-to-work program requires leveraging of existing resources. Two primary strategies will be pursued:

(i) Revitalize the public housing neighborhood by attracting public and private investment for business or commercial development and create new, full-time, permanent jobs and/or business ownership opportunities in those businesses and industries for the target population affected by welfare reform. Co-applicants should be able to immediately identify existing or new businesses and industries, especially those in projected job growth areas, that would be willing to expand their activities and/or relocate into the target area, pursuant to a package of economic incentives. This will entail coordination with currently operational economic development strategies. It will also require in most instances a mix of different businesses/industries that are willing to design and dedicate a certain number and type of positions appropriate for the target population. Among the fastest growing and marketable employment growth areas in various sizes and types of American communities are property management and maintenance, education, child care, information systems, environmental services, and health care. Co-applicants are urged to focus their job development strategies in these or other documented local growth areas.

(ii) Support the participating residents in their transition to self-sufficiency by concentrating supportive services in human service centers including nearby schools and business/employer facilities, located within or in proximity to the targeted public housing development at locations that are highly visible and accessible to persons with disabilities. It is envisioned that the following essential supportive services will be available: child care, remedial and vocational education (permitted to be off-site to take advantage of local resources), job readiness preparation, transportation and other health and human resources deemed important to prepare and support the residents in their transition from welfare to work.

(2) Key elements for this two-pronged approach include:

(i) Implementing larger community-based strategic plans, such as the Empowerment Zone/Enterprise Community strategies, to optimize the use of community resources and more effectively achieve the economic and community revitalization in public housing neighborhoods.

(ii) Leveraging of existing Federal, State and local human, material, real property and financial resources (including tax abatements and related financial investment incentives) to support the revitalization activities.

(iii) Creating a child care system with linkages to other comprehensive supportive services through a plan addressing consumer education, utilization of existing resources, and development of a coordinated network of new and existing child care homes

and centers and before/after school activities.

(iv) Enhancing or developing appropriate recreational, tutoring, mentoring and related activities for children and youth located in the targeted neighborhoods.

(3) This joint initiative is particularly relevant to the Administration's mission of strengthening the American family and promoting self-sufficiency. This program has goals of increasing the access of low-income people to employment-related opportunities, improving job skills, and improving the integration, coordination, and continuity of the various services potentially available to families living in poverty.

Additional information regarding these program ingredients is contained in Appendices B and C.

(c) Funding

HUD and HHS are each making $2.5 million available for award under this joint initiative.

The Boys & Girls Clubs of America is making up to $500,000 available to selected co-applicants for after school programs and other youth development activities providing constructive environments for children of program participants.

The Departments of Housing and Urban Development, Health and Human Services, and Agriculture will provide technical assistance related to the implementation of economic and job development strategies related to EZ/EC communities, child care, employment preparation and coordinated transportation systems to facilitate the participating residents' transition from welfare-to-work efforts.

(d) Structure

This is a three year initiative. Grants will be awarded by September 30, 1997 and are expected to be underway immediately upon award. Since a comprehensive, integrated strategy is important to enable families to achieve self-sufficiency, this initiative is designed to foster collaboration between the public and private sectors. Toward this end, a number of components and features are required.

(1) Co-Applicants

Co-sponsored applications are required. The co-applicants will function as joint administrators to develop, direct, and coordinate appropriate financial and human resources. Together, they will be responsible for creating and managing the essential community-based social and economic architecture to assure successful implementation.

At a minimum, each application must have a Housing Authority (HA) and Community Development Corporation (CDC) as co-applicants to be eligible. All HAs (urban, rural, suburban, except Indian Housing Authorities) and CDCs are eligible. The co-applicants must identify a grant manager to assure effective administration and resource integration.

The required co-applicants may also, if they wish, have additional co-applicants, such as nonprofit and for-profit corporations and public bodies, including their agencies or instrumentalities.

All co-applicants must have a legal partnership evidenced by an executed Memorandum of Agreement (MOA) which delineates the partners' roles and responsibilities for grant administration. Co-applicants are considered an integral part of the application and cannot be changed once applications are submitted and under review without disqualifying an application. If a co-applicant is awarded a grant, it must obtain HUD and HHS approval prior to dissolving a partnership with a co-applicant or significantly changing its role. Dissolution of the Joint Grant is not permitted and is considered grounds for default under the Grant Agreement.

(2) Required Partnerships

The HA and CDC partners must secure partnerships with appropriate social, economic, educational, transportation, and employment readiness agencies in the public and private sector in advance of applying for the funds under this joint initiative. Through these partnerships, the public and private service providers will describe the specific resources to be provided in the targeted community, and the process for consulting with residents to assure successful implementation of programs. The specific requirements for each partnership are described in Part III, Section (a)—Threshold Requirements. Required partnerships with the HA and CDC include, but are not limited to:

(i) *Partnership with Residents:* The purpose of this partnership is to promote customer participation in the planning and implementation of the project.

(ii) *Partnership with Business/ Industry:* The purpose of these partnerships is to provide incentives for businesses or industries to locate in the target area and create new and/or expand existing job opportunities for residents affected by welfare reform.

(3) Other Partnerships

(i) *Boys & Girls Club Partnership:* Applications with a partnership with the local Boys & Girls Club to provide enhanced child care, afterschool services, or other youth development activities may receive funding from the Boys & Girls Club of America. This funding will be provided to the local Boys & Girls Club to support those activities.

(ii) *Empowerment Zone/Enterprise Community Partnership:* In addition, special consideration will be given for collaboration with Empowerment Zone/ Enterprise Community Agencies as this type of partnership can have substantial impact on the number of new jobs created in these communities.

(4) Coordination

This joint initiative will be coordinated locally through a grant manager designated by the co-applicants.

A Federal Interagency Coordinating Committee will oversee this joint initiative at the national level. An Interagency Agreement, signed by all participating Federal agencies (HUD, HHS, and USDA) outlines the administrative, legal and fiscal responsibilities agreed upon by each agency. The Coordinating Committee, constituted by program officers from each participating agency, will be responsible for the development and implementation of the grant application review, rating and selection process, and monitoring of the progress of grants, except that HHS will assume sole responsibility for any construction or renovation. The Chair of the Interagency Coordinating Committee will rotate among the participating agencies. Ultimate responsibility on grant implementation will be retained by each agency on individual grants.

(e) Promoting Comprehensive Approaches to Housing and Community Development

HUD is interested in promoting comprehensive, coordinated approaches to housing and community development. Economic development, community development, public housing revitalization, homeownership, assisted housing for special needs populations, supportive services, and welfare-to-work initiatives can work better if linked at the local level. Toward this end, HUD in recent years has developed the Consolidated Planning process designed to help communities undertake such approaches.

In this spirit, it may be helpful for co-applicants under this NOFA to be aware

of other related HUD NOFAs that have recently been published or are expected to be published in this fiscal year. By reviewing these NOFAs with respect to their program purposes and the eligibility of co-applicants and activities, co-applicants may be able to relate the activities proposed for funding under this NOFA to the recent and upcoming NOFAs and to the community's Consolidated Plan.

With respect to community and economic development, the following related NOFAs have been published: (1) The NOFA for the Community Outreach Partnership Centers (March 20, 1997, at 62 FR 13506); (2) the NOFA for the Tenant Opportunity Program—Economic Development and Supportive Services (June 6, 1997, at 62 FR 31272); and (3) the NOFA for Historically Black Colleges (May 12, 1997, 62 FR 26180).

To foster comprehensive, coordinated approaches by communities, the Department intends for the remainder of FY 1997 to continue to alert co-applicants of HUD's NOFA activity. In addition, a complete schedule of NOFAs published during the fiscal year appears under the HUD Homepage on the Internet, which can be accessed at http://www.hud.gov/nofas.html. Additional steps to better coordinate HUD's NOFAs are being considered for FY 1998.

To help in obtaining a copy of your community's Consolidated Plan, please contact the community development office of your municipal government.

Part II—Program Specifications

(a) Authority

This joint initiative is authorized pursuant to:

(1) The Community Planning and Development section of the 1997 HUD Appropriations Act entitled, ''An Act Making Appropriations for the Departments of Veteran Affairs and Housing and Urban Development, and for sundry independent agencies; boards, commissions, corporations, and offices for the fiscal year ending September 30, 1997, and for other purposes'', (P.L. 104–204, approved September 26, 1996), which provides grants to housing authorities to enable them to establish programs that increase resident self-sufficiency.

(2) The Community Initiative program is authorized by Sections 681(a) and 681(b)(1) of the Community Services Block Grant Act (42 U.S.C. sections 9910(a) and (b)(1)), as amended. Under the Community Initiative Program, the HHS Secretary is authorized to make funds available to support on-going program activities of national or regional significance to alleviate the causes of poverty in economically distressed communities with special emphasis on community and economic development activities.

(b) Definitions

Budget Period: The interval of time into which a grant period of assistance is divided for budgetary and funding purposes.

Commitment: Documented evidence in the form of a written obligation (on appropriate letterhead) specifying:

(1) The dollar amount (or value), source of funds or types of resources promised for the program, and their use in the program;

(2) The date of availability and duration of funds or other types of resources;

(3) The authority by which the commitment is made (such as board resolution, grant award notification); and

(4) The signature of the appropriate executive officer authorized to commit the resources.

Community Development Corporation (CDC): A private, nonprofit entity, governed by a board consisting of residents of community and business and civic leaders, which has as a principal purpose planning, developing, or managing low-income housing or community development projects (proof of non profit status, i.e., the IRS determination letter of tax exemption must be included.)

Community Facility: A non-dwelling structure that provides space for multiple supportive services for the benefit of public housing residents (as well as others eligible for the services provided) including but not limited to: child care, after-school activities for youth, job training, Campus of Learners activities, and English as a Second Language (ESL) classes.

Construction Projects: For the purpose of this announcement, construction projects, funded only by HHS, involve land improvements and development or major renovation of (new or existing) facilities and buildings, including their improvements, fixtures and permanent attachments. HHS will have sole responsibility for reviewing construction-related projects.

Development: Has the same meaning as the term ''Project'' below.

Distressed Community: A geographic urban neighborhood or rural community of high unemployment and pervasive poverty.

Empowerment Zones/Enterprise Communities: Those communities designated as such by the Secretaries of Agriculture or Housing and Urban Development.

Equity Investment: The provision of capital to an organization for use as working capital or for some other specified purpose in return for a portion of ownership.

Job Placement: Placing a person in an existing vacant job of a business, service, or commercial activity not related to new development or expansion activity.

Project: For an HA's purposes, is the same as ''low-income housing project'' as defined in section 3(b)(1) of the United States Housing Act of 1937 (42 U.S.C. 1437 et.)

Public Housing Agency (HA): Any state, county, municipality, or other governmental entity or public body (or agency or instrumentality thereof) which is authorized to engage in or assist in the development and operation of low-income housing.

Resident Council (RC): An incorporated or unincorporated nonprofit organization or association that consists of persons residing in public housing and that meets each of the requirements specified in 24 CFR 964.115.

Resident Management Corporation: An entity that consists of residents residing in public housing and that meets the requirements specified in 24 CFR 964.120.

Rural: An area that is not within the outer boundary of a metropolitan entity having a population of 25,000 or more and contiguous communities with a population density of 100 persons or more per square mile according to the latest decennial census. Such an area may be located entirely within one State or made up of contiguous interstate communities.

Secretary: The Secretary of Housing and Urban Development and/or the Secretary of Health and Human Services, as appropriate.

Surrounding Neighborhood: A geographic area within a jurisdiction of a unit of general local government (but not the entire jurisdiction unless the population of the unit of general local government is less than 25,000) designated in comprehensive plans, ordinances, or other local documents as neighborhood, village, or similar geographical designation, or the entire jurisdiction of a unit of general local government with a population that is less than 25,000.

Technical Assistance: A problem-solving event generally utilizing the services of an expert. Such services may be provided on-site, by telephone, or other means of communication. These services address specific problems and are intended to assist with the

resolution of a given problem or set of problems.

(c) Eligible Participants

Residents of public housing and residents in the surrounding neighborhood who are below the poverty line and affected by the welfare reform legislation (including AFDC/TANF recipients, legal immigrants, disabled SSI recipients, etc.) are eligible to participate in and/or receive the benefits of this grant. Section 8 tenants with certificates or vouchers or tenants in Section 8 project-based units are eligible to participate in and/or receive the benefits of this grant, as long as they are residing in the surrounding neighborhood as identified in the application. Eligible participants also include low-income residents in the neighborhood surrounding the HA project, who are displaced workers; at-risk teenagers; non-custodial parents, particularly those of children receiving AFDC/TANF assistance; individuals who are homeless; and those with developmental disabilities.

Projects proposed for funding must result in direct benefits to low-income people as defined in the most recent Annual Revision of Poverty Income Guidelines published by HHS (See Appendix E).

Annual revisions to the Poverty Income Guidelines are normally published in the **Federal Register** in February or early March. Grantees will be required to apply the most recent guidelines throughout the project period. These revised guidelines may be obtained at public libraries, Congressional offices, or by writing the Superintendent of Documents, U. S. Government Printing Office (GPO), Washington, D.C. 20402. No other government agency or privately-defined poverty guidelines are applicable for the determination of low-income eligibility for the OCS programs.

Note, however, that low-income individuals granted lawful temporary resident status under Section 245A or 210A of the Immigration and Nationality Act, as amended by the Immigration Reform and Control Act of 1986 (Public Law 99–603) may not be eligible for direct or indirect assistance based on financial need under this program for a period of five years from the date such status was granted.

(d) Maximum Grant Amounts

(1) The maximum combined grant awards are estimated to be as follows:

(i) For housing authorities with 1 to 1,250 units, the maximum grant award is $400,000 in combined HHS/HUD funds.

(ii) For housing authorities with 1,251 to 10,000 units, the maximum grant award is $600,000 in combined HHS/HUD funds.

(iii) For housing authorities with more than 10,000 units, the maximum grant award is $1.2 million in combined HHS/HUD funds.

(2) **Note:** HUD and HHS funds will be awarded to HAs and CDCs respectively. Budgets must therefore be broken down to separate HUD/HHS funds. Amounts may or may not be equal in sum from HUD/HHS.

(e) Matching Requirements

HUD funds must be matched dollar-for-dollar (100%) in either in-kind (including contributions of personnel, space and/or equipment) or in cash. HHS funds do not require any matching contribution. If a match is included, grantees will be held accountable and a disallowance could result from failure to meet the match. See Part III, Section (a), Item 8 (Leveraging Other Resources) for more detailed information.

(f) Eligible Activities

Please note that grantees will need to establish separate books of account for any specific funding sources, including the two prime Federal programs. Under OMB Cost Circulars (A–87, A–21, A–110, and A–122), grantees may not duplicate funding from (i.e., charge the same costs to) this joint grant and any other funding sources, although the costs of budget line items may be shared between the grant and other funding sources in accordance with allocation criteria in the applicable OMB Cost Circular. Adequate financial controls must be in place to assure compliance with these requirements.

While an array of eligible activities, as described below, can be funded with HHS resources, the activities must be linked directly to the development of new employment opportunities and/or the preparation and support of the individuals that will be employed in the new jobs. ''Job creation'' means new jobs that are realized as a result of an HHS funded project. This includes the development of either new or expanding business, service, physical and commercial activities. The jobs created must not have been in existence prior to the start of the project. Job creation is to be distinguished from job placement services which are concerned with the placing of a person in an existing vacant job or business, service or commercial activity not related to new development or expansion. Following is a description of eligible activities:

(1) *Economic Development activities* includes activities essential to facilitate job creation and economic uplift and provide access to the skills and resources needed for self-development and business development. HUD funds, however, cannot be used toward capital costs for acquisition, construction, and equipment. Economic development activities may include:

(i) Entrepreneurship training (e.g., literacy training, computer skills training, business development planning);

(ii) Entrepreneurship development (e.g., entrepreneurship training curriculum, entrepreneurship courses);

(iii) Job creation activities (i.e., new jobs which result from new or expanded businesses, services, or commercial activities). For OCS funding, the jobs created must not have been in existence prior to the start of the project;

(iv) Micro/Loan fund entails developing a strategy for establishing a revolving micro loan fund and/or capitalizing a loan fund. A loan fund (from non-grant funds and/or grant funds) may be included as part of a comprehensive entrepreneurship training program. HHS/OCS funds may not be used to establish or expand revolving loan funds;

(v) Developing credit unions entails creating on-site credit union(s) to provide financial and economic development initiatives to HA residents. The credit union could support the normal financial management needs of the community (i.e., check cashing, savings, consumer loans, micro-businesses and other revolving loans); HUD funds cannot be used to capitalize a credit union. HHS/OCS funds cannot be used for any type of credit union activity.

(vi) Employment training and counseling (e.g., job training, preparation and counseling, job search assistance, job development and placement, and continued follow-up assistance after job placement); and

(vii) Employer linkage and placement includes collaboration with area employers to determine job placement and training issues and on-going follow-through with residents placed in training or full-time positions; please note that HHS/OCS funds for economic development are limited to providing job related training for newly created (not existing) jobs; program components involving training and placement in existing vacant positions are not eligible for HHS/OCS funding.

(2) *Supportive Services* entail the provision of services to assist eligible residents become economically self-sufficient, particularly families with children where the head of household would benefit from the receipt of

supportive services and is working, seeking work, or is preparing for work by participating in job-training or educational programs. Please note that HHS funding is restricted to activities related to new job creation as discussed above, under Economic Development Activities. Supportive services may include:

(i) Child Care, of a type that provides sufficient hours of operation and serves appropriate ages as needed to facilitate parental access to education and job opportunities, and ensure the healthy development of children. Categories of care include center-based child care, family child care and in-home child care;

(ii) Employment training and counseling (e.g., job training such as apprenticeship programs, job preparation and counseling, job search assistance, job development and placement, and continued follow-up assistance after job placement);

(iii) Computer-based educational opportunities, skills training, and economic development activities;

(iv) Education (e.g., remedial education, literacy training, assistance in the attainment of certificates of high school equivalency, trade school assistance, two-year college tuition assistance, youth leadership skills and related activities). Activities may include peer leadership roles training for youth counselors, peer pressure reversal, life skills, goal planning;

(v) Youth mentoring of a type that mobilizes a potential pool of role models to serve as mentors to public housing youth. Mentor activities may include after-school tutoring, drug abuse treatment, job counseling or mental health counseling;

(vi) Transportation costs, as necessary to enable any participating family member to commute to training, supportive services' activities and/or place of employment, including but not limited to assessing needs and resources, purchase of transit passes, joint purchase of vehicles with local transit providers, assistance with vehicle repairs and maintenance;

(vii) Personal welfare (e.g., family/parental development counseling, parenting skills training for adult and teenage parents, substance/alcohol abuse treatment and counseling, and self-development counseling, etc.);

(viii) Supportive health care services (e.g., outreach and referral services); and

(ix) Any other services and resources that are determined to be appropriate in assisting eligible residents.

(3) *The employment of service coordinator(s)/case manager(s).* For the purposes of this NOFA, a service coordinator/case manager is any person who is responsible for one or more of the following functions:

(i) Assessing the training and supportive service needs of eligible residents;

(ii) Working with community service providers to coordinate the provision of services and to tailor the services to the needs and characteristics of eligible residents;

(iii) Monitoring and evaluating the delivery, impact, effectiveness and outcomes of supportive services under this program;

(iv) Coordinating this program with other self-sufficiency, education and employment programs;

(v) Performing other duties and functions that are appropriate to assist eligible public housing and other neighborhood residents to become self-sufficient;

(vi) Mobilizing other national and local public/private resources and partnership; and

(vii) Any other services and resources proposed by the co-applicant and approved by the co-sponsors that are determined to be appropriate in assisting eligible residents.

(g) Term of Grant/Period of Availability of Funds

With certain exceptions of HHS grant funds, all funds must be expended within three years (36 months) after the effective date of grant agreement. Grant implementation progress must be evident and documented within the first six (6) months of grant award. Grantees must have completed all but grant close-out activities within 30 months after the effective date of the grant agreement. Grant terms may not be extended without substantial good cause (circumstances reasonably unforeseen and reasonably beyond the grantee's control) and are subject to approval by HUD and HHS. Concerning HHS grant funds, co-applicants with projects involving construction only may request project and budget periods of up to 36 months. Co-applicants for non-construction projects under these priority areas may request project and budget periods of up to 17 months.

Part III—Application Process

Each application that is submitted in a timely manner to the HUD Headquarters Office of Community Relations and Involvement and that otherwise meets the requirements of this NOFA will be evaluated competitively on a joint basis by the sponsoring Federal agencies under the auspices of the Federal Interagency Coordinating Steering Committee using a point scale.

Co-applicants may submit only one application package under this NOFA (See Appendix A for each co-applicant's submission within a consolidated package). The proposed funding can be no more than the cost limits described in Section I.(e) above.

(a) Threshold Requirements

The following information must be contained in the application as threshold requirements to be considered essential for rating and ranking as discussed in Section III.(b) of this NOFA.

(1) Joint Application

The application must be jointly submitted by the HA and the CDC, and there must be an MOA between the two organizations.

(2) Needs Assessment Report

The application must contain a report on the proposed recipient population that includes, at minimum, sections containing statistical or survey information that addresses the economic status of the target and surrounding area (including a description of local business conditions), the relative needs of the recipient population in the affected community(s) to be served, and an identification of economic strategies and supportive services resources to meet the needs. The Needs Assessment Report must include supporting data to justify the economic needs of the development/neighborhood to be served, the viability of existing businesses in the area and prospective opportunities for job growth, and identified businesses or industries which are under-represented in the area that could improve the economic vitality of the neighborhood.

(3) Grant Implementation Plan

The application must contain a grant implementation plan (See Appendix A). The plan must be based on a thorough examination of the public housing and adjacent neighborhood needs and resources and address a portion of the needs in the Needs Assessment Report. The plan must, at a minimum, include the following:

(i) A component promoting training, employment and contracting opportunities through the HA (in accordance with section 3 of the Housing and Urban Development Act of 1980; see 24 CFR part 135);

(ii) A brief description outlining how the plan conforms to the applicable state AFDC/TANF and child care plans, community economic development strategies and job creation efforts.

(iii) A business plan (can be an existing or a new business plan);

(iv) Specific measurable objectives (such as the objective of 200 residents being employed, 10 resident businesses started, and 250 residents completing GED requirements) to be achieved as a result of grant activities;

(v) Major milestones and activities necessary to accomplish the goals;

(vi) A timetable for accomplishing activities;

(vii) A detailed budget;

(viii) A description of how resources and/or services firmly committed by the co-applicants and other partners are effectively directed to support the residents self-sufficiency efforts and how they will be provided for at least three years. To be considered firmly committed there must be a written agreement to provide the resources. These resources must be provided for a period of at least three years. The written agreement may be contingent upon a co-applicant receiving a grant award;

(ix) Identification of a grant manager, selected by the co-applicants, to assure effective administration and resource integration.

(x) Identification of HA development(s) and surrounding neighborhoods to be assisted under this joint initiative.

(4) Required Partnerships

(i) *Partnership with Business/ Industry:* The application must contain signed commitments from businesses or industries that intend to participate describing how these businesses/ industries will create new and/or expand existing job opportunities for residents in the target area. The following specific features must be included:

(A) Jobs to be created will accommodate the projected number of AFDC/TANF and other residents affected by welfare reform targeted for employment. This does not suggest that a single business/industry must employ only AFDC/TANF residents or absorb all the targeted population. It is anticipated that a variety of businesses/ industries will be needed to produce the appropriate number and type of employment opportunities.

(B) The co-grantees will have authority to screen co-applicants for jobs to be filled by AFDC/TANF recipients and to verify their eligibility.

(ii) *Partnership with Residents:* The application must contain a written commitment to involve residents of the target area in plan development and implementation, and a corresponding commitment from appropriate resident groups. The residents may be represented by a Resident Council, Resident Management Corporation, or applicable neighborhood association or tenant organization. Also, experience with such collaborations should be described.

(iii) *Partnership with a Boys & Girls Club* (if B&GCA funds are sought):

The application must contain a Memorandum of Agreement (MOA) between the co-applicants and the appropriate Boys & Girls Club that will be providing enhanced services to the HA communities. Boys & Girls Club funds are added on and will be provided to the co-applicants' awarded funds.

(5) Welfare and Child Care Plan Linkage

The application must provide documentation from the appropriate State welfare agency that the proposed Grant Implementation Plan is consistent with the State TANF (welfare) and Child Care Plans or the State's proposed plans to date. In order to be consistent with these State plans, the implementation plan must have a performance objective that would result in a majority of the participants becoming self-sufficient and working by the deadline for the termination of AFDC/TANF assistance set by the State. In addition, the co-applicants' plan must be guided by the goals, objectives and schedules of the State TANF plan both overall and to the extent that such goals, objectives and schedules are set for individual families. With respect to time limits, the co-applicants must, however, comply with the restrictions of this joint initiative if its requirements conflict with those of the State Welfare plan. For example, the State Welfare Plan may give the AFDC/ TANF recipients five years to leave public assistance, but this joint program is to be completed within three years regardless.

(6) Focus on Residents affected by Welfare Reform

The application must provide written evidence from the co-applicants that all (100%) of area residents to be targeted in the proposed program are affected by the welfare reform legislation, including AFDC/TANF recipients, legal immigrants, and disabled SSI recipients.

(7) Accessible Community Facility(s)

The application must contain evidence (e.g., through a use agreement) that a preponderance of the proposed activities will be administered at community facilities in or within easy access of the specific public housing development(s). These facilities must be accessible to persons with disabilities. This may include deprogrammed units, existing community space or off-site facilities, such as a neighborhood school. If units have to be converted from dwelling use into a community facility or a facility to be constructed, the co-applicants must submit a plan for the conversion or construction that provides for adequate resourcing and a time schedule. Only HHS funds may be used for construction or renovation. If the proposed community facility is to be provided by an entity other than the co-applicants, the application must include an agreement with the proper authority (owner or operator of the site) for use of the proposed facility. The community facilities must be operational within nine (9) months of the grant award. In the case of applications for programs to be implemented for the primary benefit of residents in housing that is dispersed in a rural setting, the co-applicants must provide evidence that participants will have access to transportation to the facility that is convenient. This community facility requirement also shall not apply to reverse commute activities that provide transportation to jobs that are distant from the dwellings of participants.

(8) Leveraging Other Resources (Matching Requirements)

(i) For HUD-sponsored funds, the application (including the budget, narrative, and other Memoranda of Agreement (MOAs)) must clearly evidence firm commitments for non-grant resources and services equal to the HUD grant amount proposed in the application. These resources and services can include commitments from HUD's Comprehensive Grant, all other governmental units/agencies of any type and/or private sources, whether for profit or nonprofit. However, current HUD/Economic Development and Supportive Services and HHS/ Community Services funds do not qualify as a part of the match. The match amount may consist of a monetary commitment of funds, such as in-kind or other types of contributions. The remainder of the one for one match can consist of personnel, space, and/or equipment.

(ii) For HUD, the following are OMB guidelines for valuing certain types of in-kind contributions:

(A) The value of volunteer time and services shall be computed at a rate of five dollars per hour except that the value of volunteer time and service involving professional and other special skills shall be computed on the basis of the usual and customary hourly rate paid for the service in the community where the joint initiative is located;

(B) The value of any donated material, equipment, building, or lease shall be computed based on the fair market value at time of donation. Such value shall be documented by bills of sales, advertised prices, appraisals, or information for comparable property similarly situated not more than one-year old taken from the community where the item or program is located, as appropriate.

(iii) No match is required for HHS funds. However, if a match is included, third party in-kind contributions are defined as the value of non-cash contributions provided by non-Federal third parties which may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefitting and specifically identifiable to the project or program. Also, grantees will be held accountable and a disallowance could result from failure to meet match.

(9) PHMAP Score

An HA co-applicant must provide documentation that its last Public Housing Management Assessment Program (PHMAP) score included an overall ''B'' average, as well as a ''C'' on Indicator #7, Resident Services and Community Building, and a ''C'' on Indicator 6(a), Operating Reserves. (See 24 CFR Part 901 published December 30, 1996.) If the HA's most recent PHMAP score was based on the prior PHMAP regulation, the HA must provide documentation that its overall score included an overall ''B'' average, as well as a ''C'' on Indicator #11, Resident Initiatives, and at least a ''C'' on Indicator #9, Operating Reserve. No HA co-applicant designated as ''troubled'' as a result of its most recent PHMAP score is eligible for this initiative.

(10) Audit Findings and Equal Opportunity

The co-applicants cannot have unresolved, outstanding audit findings or fair housing and equal opportunity monitoring review findings or field office (for HUD)/Regional office (for HHS) management review findings related to discriminatory practices. In addition, the co-applicants must be in compliance with civil rights laws and equal opportunity requirements. Co-applicants will be considered to be in compliance if:

(i) As a result of a formal administrative proceeding, there are no outstanding findings of non-compliance with civil rights laws or the co-applicants are operating in compliance with a Federally-approved compliance agreement designed to correct the area(s) of non-compliance.

(ii) There is no adjudication of a civil rights violation in a civil action brought against them by a private individual, or the co-applicants demonstrate that they are operating in compliance with a court order, or implementing a HUD-approved selection and assignment plan or compliance agreement, designed to correct the area(s) of non-compliance.

(iii) There is no deferral of Federal funding based on civil rights violations.

(iv) HUD has no deferred application processing by HUD under Title VI of the Civil Rights Act of 1964 942 U.S.C. 2000d–1) (Title VI), the Attorney General's Guidelines (28 CFR 50.3) and HUD's Title VI regulations (24 CFR 1.8) and procedures (HUD Handbook 8040.1) or under Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (Section 504) and HUD's implementing regulations (24 CFR 8.57);

(v) There is no pending civil rights suit brought against the co-applicants by the Department of Justice; and

(vi) There is no unresolved finding of discrimination against the co-applicants issued under section 810 of the Fair Housing Act (24 U.S.C. 3601–3619), as implemented at 24 CFR 103.400.

(11) Automated Capability

The application must provide certification that the program will include access to on-line computer/internet capability as a means of communication with HUD on grant matters.

(12) Compliance With Current Programs

The co-applicants must provide certification that they are not in default at the time of application submission with respect to applicable grant programs funded by HUD and HHS. Such compliance may be waived if the co-applicants provide sufficient evidence that any aspects of non-compliance with prior grants were beyond their control, such as a natural disaster.

(b) Selection Criteria

Each application for a grant award submitted in a timely manner, as specified in this NOFA, that otherwise meets the threshold and other requirements of this NOFA will be evaluated competitively using a point scale. The number of points that an application receives will depend on how well it addresses the selection factors described below. HUD and HHS program components of the applications will be scored on the following factors:

(1) FACTOR I: Quality of Planning for Community-Building/Economic Development (maximum points: 40)

(i) *Needs Assessment Report* (maximum points: 5)

A description of the proposed target neighborhood containing a socio-demographic profile of the residents, an economic assessment of the area's business development and growth, and a brief discussion of the current social problems, available resources and corresponding service needs of the resident population. Up to five (5) points will be awarded based on the quality and comprehensiveness of the needs assessment document and its discussion of existing and potential businesses and job opportunities in the community. In order to obtain maximum points, this document must contain statistical data which provides:

(A) A socio-economic profile of the eligible residents in relationship to relevant jurisdictional and national data on the following: AFDC/TANF, SSI, and other fixed income arrangements; in job training or entrepreneurship and community services programs; in resident owned businesses; and those employed. Specific information should be provided on training, contracting and employment through the HA.

(B) An assessment of the current economic situation in the target area and within the surrounding community, including current economic and job development strategies, and their current status and effectiveness.

(C) An assessment of the current service delivery system as it relates to the needs of the target population, including the number and type of services, the location of services, and community facilities currently in use.

(D) A timetable of the proposed plan to address the needs identified in the assessment report. The timetable should cover the three-year period of the grant term and include the planning and implementation phases of the support services to be provided to the target population and how such services and objectives can be met in the limited time frame.

(ii) *Grant Plan Implementation Strategies* (maximum points: 35)

A description of the co-applicants' proposed plan to address the goals of the initiative within the target neighborhood within the grant period. The score on this factor will be based on the viability and comprehensiveness of the strategies proposed to meet the unmet need in the following areas: economic development/job creation, including a business plan, as well as welfare-to-work and other necessary supportive services and strategies.

(A) Economic Development/Job Development Strategies (maximum points: 10)

The score in this factor will be based on the extent and comprehensiveness of economic development/job development strategies to be provided. A high score will be received if there is a comprehensive description of the economic and job development strategies with accompanying business plan(s) that explains how the co-applicants' plan provides the additional economic opportunities and creates new jobs for targeted residents affected by welfare reform in the three-year time frame of the grant program. Briefly, the plan should describe the key work tasks and show how the project objectives will be accomplished including the development of business and creation of jobs for welfare recipients (AFDC/TANF) during the allowable OCS project period. It is anticipated that co-applicants responding to this announcement will be using existing economic development/business plans initiated under other public or private developmental efforts (e.g., EZ/EC strategies) rather than attempting to develop a completely new strategy. As a result, the Business Plan Guideline in Appendix D is provided to assist the co-applicants in assessing the completeness of the existing plans rather than the development of new ventures in response to this initiative.

(B) Supportive Services Strategies (maximum points: 6)

The score in this factor will be based on the comprehensiveness of services that will be provided. A high score is received if there is a comprehensive description of how the co-applicants' plan provides the core services that specifically address the unmet resident needs to successfully transition from welfare to work AFDC/TANF recipients. In addition, the plan's description should discuss how the planned supportive services relate to the existing economic and business resources of the community, as identified in the needs assessment report. To receive a high score, co-applicants should include case management/counseling, job training/development/placement (and/or business training/development/start-up), child care and transportation. To obtain maximum points the services must be located in the community facility(ies) (services may be provided at more than one community facility) and be available on a 12-hour-day basis or as needed by the eligible residents.

(C) Resident Contracting and Employment Strategies (maximum points: 5)

The score in this factor will be based on the extent to which residents will achieve self-sufficiency through the HA co-applicant contracting with resident-owned businesses and through resident employment. A high score will be awarded where there is documentation (letter or resolution) describing the HA's commitment to hire or contract with a substantial number of residents and a narrative describing the number of jobs or contracts, as well as the training processes related to the grant implementation plan.

(D) Work Incentive Strategies including Rent Reform and Occupancy Incentives (maximum points: 4)

The score in this area will be based on the degree to which the co-applicants have implemented or propose to implement or collaborate with the State AFDC/TANF agency to implement work incentive initiatives designed to promote resident self-sufficiency. These work incentives could include, but are not limited to, rent strategies such as income disregards, ceiling rents, rent escrows [1], occupancy preferences for co-applicants who work or are in a self-sufficiency program and stipends. A high score is received if the co-applicants can show how various incentives, including but not limited to rent escrows and/or occupancy preferences for co-applicants who work or who are in a self-sufficiency program, complement other aspects of the program implementation plan.

(E) Budget Appropriateness and Reasonableness (maximum points: 5)

Funds requested are commensurate with the level of effort necessary to accomplish the goals and objectives of the project. The application must include a detailed budget breakdown for each of the budget categories prescribed in the standardized application forms. The co-applicants must present reasonable administrative costs for each component within a 15% cap as a guideline. The estimated cost to the government of the project must also be reasonable in relation to the anticipated results.

(F) Reasonableness of the Timetable (maximum points: 5)

The score in this factor will be based on the speed at which the co-applicants can realistically accomplish the goals of the proposed program. To receive a high score the co-applicant must demonstrate that it will make substantial progress within the first six months after grant execution, including putting staff in place, finalizing partnership agreements, completing the development of requests for proposals and achieving other milestones that are prerequisites for implementation of the program. In addition, the co-applicants must demonstrate that the proposed timetable for all components of the proposed program is reasonable considering the size of the grant and its activities and that it can accomplish its objectives within the 36 months of the grant term.

(2) *Factor II: Co-Applicant's Organizational Structure for Administering Grant Activities* (maximum points: 35)

In assessing this factor, the following will be considered:

(i) *Proposed Program Staffing* (maximum points: 5)

The score in this factor will be based on the extent to which the co-applicants' proposed staffing in support of the program is suited to accomplishing the program's objectives in terms of the appropriateness of staff/consultant skills, assignments, and level of responsibility. In order to receive a high score, the co-applicants must provide a comprehensive description of who will provide the services and how the services identified will be delivered. This should include an organizational chart, proposed staff/other resources/consultants proposed, and a discussion of coordination among various services providers.

(ii) *Program Administration* (maximum points: 10)

The score in this factor will be based on the soundness of the proposed management of the program. In order to receive a high score, the application must contain a comprehensive description of the project management structure, including the use of a grant manager. The narrative must provide a description of how any other co-applicants, subgrantees and other partner agencies relate to the program administrator as well as the lines of authority and accountability among all components of the proposed program.

(iii) *Fiscal Management* (maximum points: 5)

The score in this factor will be based on the soundness of the co-applicants' proposed fiscal management. In order to receive a high score the co-applicants must provide a comprehensive description of the fiscal management structure, including but not limited to budgeting, fiscal controls and accounting as well as procedures for tracking the contributions from the participating state and local public and private partners. The application must explain the staff responsible for fiscal

[1] Unlike the FSS program, HUD will not subsidize the rent escrows so that the PHA or some other source would need to fund the escrow amounts.

management, and the processes and timetable for implementation during the proposed grant period.

(iv) *Program Evaluation* (maximum points: 5)

The score in this factor will be based on the quality of the co applicants' plan to assess the progress and success of the proposed program from the inception of the program, during program implementation, as well as at the end of the grant. In order to receive a high score, the application must contain a comprehensive description of the program evaluation system, including staff designated for the program quality controls, performance measures, use of automated systems for collecting the program data, and timetable for undertaking this activity. The performance measures must be related to the specific goals and objectives of the proposed program and could include but not be limited to the following: the number of residents starting jobs or entrepreneurship training programs, the number of residents successfully completing job training, or starting businesses, the number of residents receiving supportive services (specified by type of service), the number of community facilities used for welfare to work and other self-sufficiency/independence efforts, and the number of community partnerships executed in support of self-sufficiency for residents.

(v) *Track Record* (maximum points: 10)

The score in this factor will be based on each of the co-applicants' prior performance in successfully carrying out grant programs to assist residents in increasing their self-sufficiency and in building a community economic base. Co-applicants with no prior experience in operating programs that foster self-sufficiency and economic development will receive a score of 0 on this factor.

(A) For the HA co-applicant (up to 5 points), prior performance will include but not be limited to the following grant programs for the HA co-applicant: the Family Investment Center Program (FIC), the Youth Development Initiative under FIC, the Youth Apprenticeship Program, the Apprenticeship Demonstration Program in the Construction Trades Program, the Urban Youth Corps Program, the HOPE I Program, the Public Housing Services Coordinator Program, the Public Housing Drug Elimination program, the Youth Sports Program. Performance on the Family Self-Sufficiency Program will be rated as well, whether or not the PHA has received a grant for service coordination.

(B) For the CDC co-applicant (up to 5 points), prior performance will include but not be limited to projects previously undertaken that have provided permanent benefits to the low income population; whether the co-applicant has demonstrated the ability to implement major activities in such areas as business development, commercial development, physical development, or financial services, and the ability to mobilize dollars from sources such as the private sector (corporations, banks, etc.), foundations, the public sector, including State and local government, or individuals. The applicable grant programs include the Discretionary and Job Opportunities for Low Income Individuals (Joli) Grants. In order to receive a high score, the co-applicant must demonstrate compliance and successful implementation of any applicable grant programs (including those listed above).

(3) Factor III: Partnerships (maximum points: 25)

(i) *Overall Partnerships* (maximum points: 20)

The score in this factor will be based on the successful integration of partners into implementation of the proposed joint initiative. In order to receive a high score, the co-applicants must provide signed Memoranda of Agreement (MOA)—or equivalent signed documentation provided that it delineates the responsibilities of each of the parties and the benefits they will receive—that delineate specific partnerships related to the components in the grant implementation plan. In assessing this factor, a number of aspects of the proposed partnership will be examined including:

(A) The appropriateness of the level of expertise of the partners related to activities proposed in the application;

(B) The soundness of the division of responsibilities/management structure of the proposed partnership relative to the expertise and resources of the partners;

(C) The extent of the commitment of the partners (such as, time, resources, and funds); and

(D) The extent to which the partners, and the partnership as a whole, addresses a broader level of unmet resident needs; and the extent to which the addition of the partners provides the ability to meet needs of the co-applicants that could not otherwise be met without the partners.

(ii) *EZ/EC Partnership* (maximum points: 5)

The co-applicants will receive up to 5 points based on the criteria specified under Factor III(i), above, if they show a partnership with an EZ/EC organization.

(c) Selection Processing

(1) Corrections to Deficient Applications

After the submission deadline date, each application will be screened to determine whether it is complete, consistent, and contains correct computations.

(i) Co-applicants will be notified, in writing, of any curable technical deficiencies in the application that must be completed before the grant is awarded.

(ii) Curable technical deficiencies relate to items that:

(A) Are not necessary for review under threshold/selection criteria/ ranking factors; and

(B) Would not improve the quality of the co-applicant's program proposal.

(C) An example of a curable technical deficiency would be the failure of a co-applicant to submit a required assurance, certification, co-applicant data form, summaries of written resident comments, incomplete forms or lack of required signatures, appendices and documentation referenced in the application or a computational error based on the use of an incorrect number(s) such as incorrect unit counts.

(iv) An example of a non-curable defect or deficiency would be a missing SF–424A (Budget Information).

(2) Scoring

Each application that meets the requirements of this NOFA will be evaluated jointly by the sponsoring Federal agencies using a review process. Points will be awarded on the basis of the quality and responsiveness of the application in addressing the selection criteria for the program. Components will each be evaluated according to the selection criteria in Part III, Section (b). The two scores will be averaged and ranked on a national basis. Awards shall be made in ranked order, until all funds are expended. HUD/HHS will select the highest ranking applications that can be fully funded. However, in the event Departments determine that the available funds exceed quality projects, the Departments will not fund projects that are poor in quality.

(3) Post Selection Administration

(i) All awards will be made to fund fully an application, except as follows: The co-sponsors may approve an application for an amount lower than the amount requested, withhold funds after approval, adjust line items in the proposed grant budget within the amount requested and/or the grantee

will be required to comply with special conditions added to the grant agreement, in accordance with 24 CFR 85.12 (HAs), as applicable, and the requirements of this NOFA, or where:

(A) HUD/HHS determine that the amount requested for one or more eligible activities is not supported in the application, and/or is unreasonable or unnecessary;

(B) The application does not otherwise meet applicable cost limitations established for the program;

(C) The co-applicants have requested an ineligible activity; an activity proposed for funding does not qualify as an eligible activity and can be separated from the budget;

(D) Insufficient amounts remain in that funding round to fund the full amount requested in the application and HUD/HHS determines that partial funding is a viable option; or

(E) For any other reason where good cause exists.

(ii) Grantees are required to attend a HUD/HHS sponsored training specifically designated for grantees under this program. The sponsoring Departments intend to offer this training session within four months of grant award.

Part IV—General Grant Requirements

In addition to the requirements set forth in this NOFA, grantees are responsible for ensuring that grant funds are administered in accordance with all applicable laws and regulations, OMB circulars, fiscal and audit controls, grant agreements, grant special conditions, the grantee's approved budget (SF 424A), and supporting budget narrative, plan and activity timetable. Applicable Federal laws include but are not limited to those related to fair housing and equal opportunity and the following:

(a) Grant Administration

The policies, guidelines, and requirements of the following apply to this NOFA:

(1) For HAs and any governmental co-applicants/subgrantees/partners: 24 CFR Part 85, OMB Circular A–87 and 24 CFR Part 44;

(2) For CDCs or other private non-profit grantees or co-applicants/sub-grantees/partners: 45 CFR Part 74 and OMB Circulars A–110 or A–133; and

(3) For-profit participants: 24 CFR Part 84 and Federal Acquisition Requirements (FAR).

(b) Cost Principles

The cost principles of OMB Circulars A–87, A–21, A–110 or A–122, as applicable to the specific entity incurring the cost, apply to co-applicant grantees and subgrantees funded under this NOFA.

(c) Ineligible Contractors

The provisions of 24 CFR Part 24 (HA's) and 45 CFR Part 76 (CDC's) relating to the employment, engagement of services, awarding of contracts, or funding of any contractors or subcontractors during any period of debarment, suspension, or placement in ineligibility status apply to those co-applicant grantees and sub-grantees funded under this NOFA.

(d) Freedom of Information Act

Applications submitted in response to this NOFA are subject to disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. 552.

(e) Grant Staff Personnel

For HUD grant purposes, all persons or entities compensated by grants for services provided under a grant must meet all applicable personnel or procurement requirements and shall be required, as a condition of employment, to meet relevant State, local government, insurance, training, licensing, civil rights, or other similar standards and requirements.

(f) Grant Agreements

After an application has been approved, each co-applicant shall enter into a Grant Agreement setting forth the amount of the grant and its applicable terms, conditions, financial controls, payment mechanism and special conditions, including sanctions for violation of the agreement. Except as otherwise specified in the Grant Agreement, the co-applicant's entire application, including but not limited to the budget, timetable, and narrative will be incorporated in the Grant Agreement.

(g) Duplication of Funds

Under OMB Cost Circulars (A–87, A–21, A–110, and A–122), grantees may not duplicate funding from (i.e., charge the same costs to) this joint grant and any other funding sources, although the costs of budget line items may be shared between the grant and other funding sources in accordance with allocation criteria in the applicable OMB Cost Circular. Adequate financial controls must be in place to assure compliance with these requirements.

(h) Risk Management

Co-Grantees are required to implement, administer and monitor programs so as to minimize the risk of fraud, waste, abuse, and liability for losses from adversarial legal action. The following requirements address these concerns:

(1) Insurance/Indemnification

Each grantee shall obtain adequate insurance coverage to protect itself against any potential liability arising out of the eligible activities under this part.

(2) Failure to Implement Program

If the grant plan, approved budget, and timetable, as described in the approved application, are not operational within 90 days of the grant agreement date, the grantee must report by letter to the designated grant monitors in HUD/HHS the steps being taken to initiate the plan and timetable, the reason for the delay, and the expected starting date. Any timetable revisions that resulted from the delay must be included. The designated monitors will determine if the delay is acceptable, approve/disapprove the revised plan and timetable, and take any additional appropriate action.

(3) Default

HUD/HHS may impose sanctions, subject to notice and the co-grantee opportunity to respond/correct as described in the grant agreement if the co-grantees:

(i) Are not complying with the requirements of this part or any other Federal laws or requirements;

(ii) Fail to make satisfactory progress toward their program goals, as specified in their plan and reflected in performance or financial status reports or through other information available to the co-sponsors;

(iii) Do not establish procedures that will minimize the time lapsing between drawdowns and disbursements of funds (45 CFR 74.21(b)(5));

(iv) Do not adhere to grant agreement requirements or special conditions;

(v) Propose substantial plan changes to the extent that, if originally submitted, the application would not be selected for funding;

(vi) Engage in improper award or administration of grant subcontracts;

(vii) Do not submit reports; or

(viii) File false certification.

(4) Sanctions

The sanctions that may be imposed include but are not limited to:

(i) Temporarily withhold cash payments pending correction of the deficiency by the grantees or subgrantee(s);

(ii) Disallow all or part of the cost of the activity or action not in compliance;

(iii) Wholly or partly suspend or terminate the current award for the co-grantees' program;

(iv) Require that some or all of the grant amounts be remitted to HUD and/or HHS;

(v) Condition a future grant(s) and/or elect not to provide future grant funds to the co-grantees until appropriate actions are taken to ensure compliance;

(vi) Withhold future awards for the program; or

(vii) Take any other remedies that may be legally available.

(i) Treatment of Income

For policies pertaining to treatment of income for public housing and Section 8 families, see 24 CFR, Part 5, Subpart F.

(j) Reports and Closeout

(i) Semi-Annual Reports

Each grantee (HA/CDC) shall submit to HUD/HHS, as applicable, a semi-annual progress report and a Form 269 (CDC) in a format prescribed by HUD and HHS that indicates program expenditures and measures performance in achieving program milestones and goals. No grant payments will be approved for grantees with overdue progress reports.

(ii) Final Reports and Closeout

As part of a grant closeout process, each joint grantee shall submit to HUD and HHS a final report in a format prescribed by the departments that reports final program expenditures and measures performance in achieving program goals.

(iii) Audits and Closeouts

HUD/HHS will make maximum use of audits required under 24 CFR part 44 and 45 (HUD); 45 CFR 74.26 and 74.71 (HHS), as applicable in conducting grant close-outs. At grant close-out, HUD grantees shall make the last audit available to HUD with the final report. For OCS grantees, a final audit report covering the total grant period will be due in compliance with the requirements of OMB Circular No. A–133.

Part V—Findings and Certifications

The following findings and certifications apply to this Initiative:

(a) Paperwork Reduction Act

The information collection requirements contained in this Notice have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), and assigned OMB control numbers 2577–0211 (the ED/SS Program) and 0970–0062 (HHS/OCS Program). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

(b) Environmental Impact

The HUD portions of this NOFA do not direct, provide for assistance or loan or mortgage insurance for, or otherwise govern or regulate real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under HUD's regulations in 24 CFR 50.19 (c) (l), the portion of this NOFA pertaining to HUD assistance is categorically excluded from environmental review under the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321).

(c) Federalism Executive Order

The General Counsel, as the Designated Official under Section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this notice will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. As a result, the notice is not subject to review under the Order. This notice announces the availability of funds to HAs and CDCs to provide economic development opportunities and supportive services to assist residents of public housing and other low-income families in the surrounding neighborhood to become economically self-sufficient, and, thus could benefit families significantly.

(d) Prohibition of Advance Disclosure of Funding Decisions

HUD's regulation implementing Section 103 of the Department of Housing and Urban Development Reform Act of 1989, codified as 24 CFR part 4, subpart B, applies to the funding competition announced today. The requirements of the rule continue to apply until the announcement of the selection of successful co-applicants. All persons including HUD and other Federal employees involved in the review of applications and in the making of funding decisions are prohibited by part 4 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any co-applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted under 24 CFR part 4. Co-applicants or Federal employees who have ethics related questions should contact the HUD Ethics Law Division (202) 708–3815. (This is not a toll-free number.)

(e) Section 102 HUD Reform Act—Documentation and Public Access Requirements

Section 102 of the Department of Housing and Urban Development Reform Act of 1989 (HUD Reform Act) and the final rule codified at 24 CFR part 4, subpart B, contain a number of provisions that are designed to ensure greater accountability and integrity in the provision of certain type of assistance administered by HUD. On January 14, 1992 (57 FR 1942), HUD published a notice that also provides information on the implementation of Section 102. The documentation, public access, and disclosure requirements of section 102 are applicable to assistance awarded under this NOFA as follows:

(i) Documentation and public access requirements

HUD/HHS will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a 5-year period beginning not less than 30 days after the award of the assistance. Material will be made available not less than 30 days after the award of the assistance. Materials will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD/HHS will include the recipients of assistance pursuant to this NOFA in its **Federal Register** notice of all recipients of assistance awarded on a competitive basis.

(ii) Disclosures

HUD will make available to the public for five years all co-applicant disclosure reports (HUD Form 2880) submitted in connection with this NOFA. Updated reports (also Form 2880) will be made available along with the co-applicant disclosure reports, but in no case for a period less than three years. All reports—both co-applicant disclosure and updates—will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15.

(f) Prohibition Against Lobbying Activities

Co-applicants for funding under this NOFA are subject to the provisions of Section 319 of the Department of Interior and Related Agencies Appropriation Act for Fiscal Year 1991, 31 U.S.C. Section 1352 (the Byrd Amendment) and to the provisions of the Lobbying Disclosure Act of 1995, P.L. 104–65 (December 19, 1995). The Byrd Amendment, which is implemented in regulations at 24 CFR part 87, prohibits applicants for Federal contracts and grants from using appropriated funds to attempt to influence Federal Executive or legislative officers or employees in connection with obtaining such assistance, or with its extension, continuation, renewal, amendment or modification. The Byrd Amendment applies to the funds that are the subject of this NOFA. Therefore, co-applicants must file a certification stating that they have not made and will not make any prohibited payments and, if any payments or agreement to make payments of nonappropriated funds for these purposes have been made, a form SF–LLL disclosing such payments must be submitted. The certification and the SF–LLL are included in the application package. The Lobbying Disclosure Act of 1995, P.L. 104–65 (December 19, 1995), which repealed Section 112 of the HUD Reform Act and resulted in the elimination of the regulations at 24 CFR Part 86, requires all persons and entities who lobby covered Executive or Legislative Branch officials to register with the Secretary of the Senate and the Clerk of the House of Representatives and file reports concerning their lobbying activities.

Co-applicants must provide a certification concerning Lobbying. Prior to receiving an award in excess of $100,000, co-applicants shall furnish an executed copy of the lobbying certification. Co-applicants must sign and return the certification with their applications.

Co-applicants must fill out, sign and date form SF–LLL, Disclosure of Lobbying Activities, if applicable.

(g) Intergovernmental Review

The HHS programs are covered under Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs. The HHS program is also subject to 45 CFR Part 100, ''Intergovernmental Review of Department of Health and Human Services Programs and Activities.''

All States and Territories except Alabama, Alaska, American Samoa, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Oklahoma, Oregon, Palau, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia and Washington have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Co-applicants from these twenty-three jurisdictions need take no action regarding E.O. 12372. Co-applicants should contact their SPOCS as soon as possible to alert them of the prospective applications and receive any necessary instructions. Co-applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the co-applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline date to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which they intend to trigger the ''accommodate or explain'' rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Mail Stop 6C–462, Washington, DC 20447.

(h) Standard Form 424

The application must contain a Standard Form 424 ''Application for Federal Assistance'' (SF–424) for each co-applicant. The SF 424 must be signed by an official of the CDC and HA applying for the grant who has authority to obligate the organization legally.

(i) Standard Form 424A

The application must contain Standard Form 424A ''Budget Information—Non Construction Programs'' (SF 424A) for each co-applicant.

(j) SF–424B ''Assurances-Non-Construction''

All co-applicants, whether or not the project involves construction, must file the Standard Form 424B, ''Assurances: Non-Construction Programs.'' Co-applicants must sign and return the Standard Form 424B. The SF 424B must be signed by an official of the CDC and HA applying for the grant who has authority to obligate the organization legally.

(k) Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

Co-applicants must make the appropriate certification. By signing and submitting the applications, co-applicants are providing the certification regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions and need not mail back the certification with their application.

(l) Certification Regarding Environmental Tobacco Smoke

CDC Co-applicants must make the appropriate certification of their compliance with the Pro-Children Act of 1994. By signing and submitting the applications, co-applicants are providing the certification regarding environmental tobacco smoke and need not mail back the certification with their applications.

(m) Certification Regarding Drug-Free Workplace Requirements

OCS applicants must fill out and return this form.

(n) Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance Number for the HUD Economic Development and Supportive Services Program is 14.853; and for the HHS Community Services is 93.570.

Dated: July 23, 1997.

Kevin Emanuel Marchman,

Acting Assistant Secretary for Public and Indian Housing, Department of Housing and Urban Development.

Donald Sykes,

Director, Office of Community Services, Department of Health and Human Services.

Appendix A

Application Checklist

Threshold Requirements

The application MUST address the following requirements in order for it to be accepted for further consideration.

	Application page number(s)
1. Joint Application (HA–CDC MOA)	
2. Needs Assessment	
3. Grant Implementation Plan	
Business Plan	
4. Partnerships	
Business/Industry	
Residents	
Welfare and Child Care Plans	
Boys & Girls Club (optional)	
Other (optional)	
5. Evidence that 100% of Target Participants are Affected by Welfare Reform	
6. Accessible Community Facility (including Use Agreement)	
7. Leveraging of Other Resources	
8. Compliance with Current Programs	
9. Evidence of Automated Capability	
10. Audit Findings and Equal Employment Opportunity Certifications	
11. PHMAP Score Requirements (HA only)	

Selection Factors

HA and CDC components will each be rated and scored on the following factors.

	Application page number(s)
1. Quality of Planning for Community Building/Economic Development:	
A. Economic/Job Development	
B. Supportive Services	
C. Resident Contracting/Employment	
D. Work Incentives	
E. Budget Appropriateness/Reasonableness	
F. Reasonableness of Timetable	
2. Co-Applicant Capability/Organizational Structure for Grant Administration:	
A. Staffing	
B. Program Administration	
C. Fiscal Management	
D. Program Evaluation	
E. Track Record	
3. Resident and Other Partnerships:	
A. Overall Partnerships	
B. EZ/EC Partnerships	

Required certifications and assurances	HA	CDC
1. Application Form (SF 424 and 424A)		
2. Proof of CDC's non-profit status evidenced by a copy of the CDC's listing in the Internal Revenue Services (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code, or by a copy of a currently valid IRS tax-exemption certificate, or by a copy of the Articles of Incorporation bearing the Seal of the State in which the corporation or association is domiciled; And proof of CDC status evidenced by providing the purposes section of the Articles of Incorporation and a list of the current Board of Directors' names, titles and addresses, copies of resumes of the project director and other key management team members, written agreements, coordination with AFDC/TANF, etc. and Single Point of Contact comments (where applicable).		
3. Assurances for Non-Construction Programs (424B)		
4. a. Certification for a Drug-Free Workplace (HUD–2880)		
b. Lobbying Disclosure Update Report (HUD–2880)		
c. Disclosure of Lobbying Activities (SF–LLL)		
d. Certification Regarding Drug-Free Workplace Requirements		
e. Certification Regarding Lobbying, Debarment, Suspension, etc., and Drug-Free Workplace Requirements		

Appendix B

Program Elements for the Joint HHS/HUD Initiative

Community Partnerships for Economic Uplift and Economic Development

A. Program Elements

Following is a description of key program elements in this joint initiative.

1. Comprehensive Service Center

The comprehensive human service center is the focal point of this initiative. It is a neighborhood-based facility located within or adjacent to a public housing facility. It contains an array of redeployed public and private resources to support the housing residents, AFDC/TANF recipients and other low-income individuals in the area. It provides social, health, education, vocational, employment readiness, child care, transportation and other appropriate services and resources important to assisting residents and others achieve self sufficiency.

2. Job Creation/Employment Readiness

In order to induce a business/industry to locate in the public housing community setting it is essential that the target population, that will constitute the labor pool, be prepared to compete for and effectively function in the available positions offered by the host businesses/industries. Important to the adequate preparation of the resident population is a clear understanding of the businesses'/industries' labor capability requirements. These should be articulated in an education and performance standards document that stipulates what preparatory training the industry requires for an eligible employment pool. The public agency would be responsible for providing the necessary training and certifying the readiness of the candidates for employment.

There is a critical need for a highly focused and intensive remedial and vocational education and employment readiness capacity to meet the demands for qualified labor by the specific industry. This often requires upgrading existing remedial and vocational education training to more effectively address the education and performance standards. In addition, it requires coordination with a variety of support services.

3. Incentive Package

In order to attract appropriate businesses and industries the cities will have to provide an incentive package. The incentive package could include:

- Cost or rent free land/buildings to locate operations;

- Local and state tax abatement packages related to land, equipment, products, utilities, etc.;
- Assistance in developing and/or renovating the physical facilities and the affected transportation arteries and systems;
- Assistance in obtaining low interest loans to purchase equipment and inventory;
- Increased law enforcement to ensure the safety of the employees and the property;
- Preparation and support of the resident work-force through a comprehensive education/service center on or adjacent to the work site;
- Provision of public/private salary support packages involving the use of TANF/child care and other program resources as well as Labor's employment and training funds.

4. Entrepreneurial Development

The comprehensive service delivery centers should provide directly or through linkage to the Small Business Administration's Small Business Development Centers assistance to residents and local organizations interested in entrepreneurial efforts, such as, establishing small businesses in the area. The assistance could focus on financing, marketing , production, organization, engineering and technical problems and feasibility studies as well as venture capital formation. The business development could be designed to support a broad variety of individual and corporate needs such as child care, transportation, grocery stores, grounds and equipment maintenance, restaurants, cleaners and other related services.

5. Leveraging Resources

The participating communities would be expected to dedicate a variety of public and private human, financial and material resources to implement the comprehensive service centers and the economic development and revitalization efforts.

In order to effectively package the economic development plan it will be essential that the community leverage considerable public and private financial resources and taxes and other incentives to induce significant private investment. This will require close coordination with existing economic development strategies and tactical efforts with the city and county governments as part of an Empowerment Zone and Enterprise Community effort or similar venture.

Appendix C

Developing a Child Care System

Child Care is an essential component of economic and community development. Parents cannot seek and maintain employment or training unless they have adequate child care arrangements for their children. In order to meet the needs of housing residents, the Child Care Bureau is urging housing authorities to create systems of quality child care that are readily accessible and affordable. Below are some key elements to creating child care systems.

A. Needs Assessment

In order to determine the appropriate level of need in the community, co-applicants should conduct a needs assessment of child care demand and supply. Such an assessment should be conducted in consultation with an expert on low-income child care needs such as a local Child Care Resource and Referral Agency, or a non-profit organization. The assessment would evaluate the services currently available in close proximity to the housing site, child care information resources, the training opportunities for residents entering or currently employed in child care, and the corresponding demand. Assessments of demand and supply should include breakdowns by age, type of care, and hours of care.

B. Plan

A plan should then be developed to address the findings of the needs assessment. This plan should include what type of services or job opportunities co-applicants will provide or help coordinate, to meet need. The plan should outline ways to provide child care consumer education, linkages with other services, training opportunities and provider support, jobs and direct services in either centers or family day care homes. All planned services must meet State, county, and city regulatory requirements to ensure that children are in safe and healthy child care environments. It is suggested that co-applicants also consult an expert to develop a plan, for instance before completing a use agreement; there is a need to assure the dedicated space will comply with child care licensure and other needs.

C. Coordination

Coordination with the State Child Care Administrator is necessary to be able to secure funding for services, ensure the satisfaction of health and safety standards, and to be eligible for technical assistance. The co-applicant should obtain commitment from the State Child Care Administrator, and work closely with state and local agencies to conduct the needs assessment and develop the plan.

Appendix D

Guidelines of a Business Plan

The business plan is an essential component to determine the feasibility of the economic development/job development ventures being proposed under this joint initiative and will be rated and ranked under that component of the grant implementation plan. As noted previously in this announcement, it is assumed that the business plan or plans that will be included in response to this solicitation will have been developed previously as part of other public or private development ventures. The specific business plan must address all the relevant elements as follows:

(a) *The Business and Its Industry:* This section should describe the nature and history of the business and provide some background on its industry.

(b) *Products and Services:* This section deals with the following:

(i) *Description:* Describe in detail the products or services to be sold;

(ii) *Proprietary Position:* Describe proprietary features if any of the product, e.g., patents, trade secrets; and

(iii) *Potential:* Features of the product or service that may give it an advantage over the competition.

(c) *Market Research and Evaluation:* This section should present sufficient information to show that the product or service has a substantial market and can achieve sales in the face of competition.

(d) *Marketing Plan:* The marketing plan should detail the product, pricing, distribution, and promotion strategies that will be used to achieve the estimated market share and sales projections. The marketing plan must describe what is to be done, how it will be done and who will do it. The plan should address the following topics—Overall Marketing Strategy, Packaging, Service and Warranty, Pricing, Distribution and Promotion.

(e) *Design and Development Plans:* If the product, process or service of the proposed venture requires any design and development before it is ready to be placed on the market, the nature and extent and cost of this work should be fully discussed. The section should cover items such as Development Status and Tasks, Difficulties and Risks, Product Improvement and New Products, and Costs.

(f) *Manufacturing and Operations Plan:* A manufacturing and operations plan should describe the kind of facilities, plan location, space, capital equipment and labor force (part and/or full time and wage structure) that are required to provide the company's product or service.

(g) *Management Team:* The management team is the key in starting and operating a successful business. The management team should be committed with a proper balance of technical, managerial and business skills, and experience in doing what is proposed. This section must include a description of: the key management personnel and their primary duties; compensation and/or ownership; the organizational structure; Board of Directors; management assistance and training needs; and supporting professional services.

(h) *Overall Schedule:* A schedule that shows the timing and inter-relationships of the major events necessary to launch the venture and realize its objectives. Prepare, as part of this section, a month-by-month schedule that shows the timing of such activities as product development, market planning, sales programs, and production and operations. Sufficient detail should be included to show the timing of the primary tasks required to accomplish each activity.

(i) *Critical Risks and Assumptions:* The development of a business has risks and problems and the Business Plan should contain some explicit assumptions about them. Accordingly, identify and discuss the critical assumptions in the Business Plan and the major problems that will have to be solved to develop the venture. This should include a description of the risks and the critical assumptions relating to the industry, the venture, its personnel, the product's market appeal, and the timing and financing of the venture.

(j) *Community Benefits:* The proposed project must contribute to economic, human and community development within the

project's target area. A section that describes and discusses the potential economic and non-economic benefits to low-income members of the community must be included as well as a description of the strategy that will be used to identify and hire individuals being served by public assistance programs and how linkages with community agencies/organizations administering the AFDC/TANF program will be developed.

(k) *The Financial Plan:* The Financial Plan is basic to the development of a Business Plan. Its purpose is to indicate the project's potential and the timetable for financial self-sufficiency. In developing the Financial Plan, the following exhibits must be prepared for the first three years of the business' operation:

(i) Profit and Loss Forecasts—quarterly for each year;

(ii) Cash Flow Projections—quarterly for each year;

(iii) Pro Forma Balance Sheets—quarterly for each year.

Also, additional financial information for the business operation that must be included is an initial Source and Use of Funds Statement for project funds and a brief summary paragraph discussing any further capital requirements and their sources.

Applications which propose to use the requested HHS/OCS funds to make an equity investment or a loan to a business concern, including a wholly-owned subsidiary, or to make a sub-grant with a portion of the HHS/OCS funds, must include a written agreement between the community development corporation and the recipient of the grant funds.

BILLING CODE 4210–33–P

APPENDIX E

1997 POVERTY INCOME GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Size of Family Unit	Poverty Guidelines
1	$ 7,890
2	10,610
3	13,330
4	16,050
5	18,770
6	21,490
7	24,210
8	26,930

For family units with more than 8 members, add $2,720 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above.)

1997 POVERTY INCOME GUIDELINES FOR ALASKA

Size of Family Unit	Poverty Guidelines
1	$ 9,870
2	13,270
3	16,670
4	20,070
5	23,470
6	26,870
7	30,270
8	33,670

For family units with more than 8 members, add $3,400 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above.)

1997 POVERTY INCOME GUIDELINES FOR HAWAII

Size of Family Unit	Poverty Guidelines
1	$ 9,070
2	12,200
3	15,330
4	18,460
5	21,590
6	24,720
7	27,850
8	30,980

For family units with more than 8 members, add $3,130 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above.)

APPENDIX F

OMB STATE SINGLE POINT OF CONTACT LISTING

ARIZONA

Joni Saad
Arizona State Clearinghouse
3800 N. Central Avenue
Fourteenth Floor
Phoenix, Arizona 85012
Telephone (602) 280-1315
FAX: (602) 280-1305

ARKANSAS

Mr. Tracy L. Copeland
Manager, State Clearinghouse
Office of Intergovernmental Services
Department of Finance and Administration
1515 W. 7th St., Room 412
Little Rock, Arkansas 72203
Telephone: (501) 682-1074
FAX: (501) 682-5206

ALABAMA

Jon C. Strickland
Alabama Department of
Economic and Community Affairs
Planning and Economic Development Division
401 Adams Avenue
Montgomery, Alabama 36103-5690
Telephone: (205) 242-5483
Fax: (205) 242-5515

CALIFORNIA

Grants Coordinator
Office of Planning & Research
1400 Tenth Street, Room 121
Sacramento, California 95814
Telephone (916) 323-7480
FAX (916) 323-3018

DELAWARE

Francine Booth
State Single Point of Contact Executive Department
Thomas Collins Building, P.O. Box 1401
Dover, Delaware 19903
Telephone: (302) 739-3326
FAX: (302) 739-5661

DISTRICT OF COLUMBIA

Charles Nichols
State Single Point of Contact
Office of Grants Mgmt. & Dev.
717 14th Street, N.W. - Suite 500
Washington, D.C. 20005
Telephone: (202) 727-6554
FAX: (202) 727-1617

FLORIDA

Florida State Clearinghouse
Department of Community Affairs
2740 Centerview Drive
Tallahassee, Florida 32399-2100
Telephone: (904) 922-5438
FAX: (904) 487-2899

GEORGIA

Tom L. Reid, III
Administrator
Georgia State Clearinghouse
254 Washington Street, S.W. - Room 401J
Atlanta, Georgia 30334
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(404) 656-3829
FAX: (404) 656-7938

ILLINOIS

Barbara Beard
State Single Point of Contact
Department of Commerce and Community Affairs
620 East Adams
Springfield, Illinois 62701
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FAX: (217) 534-1627

INDIANA

Amy Brewer
State Budget Agency
212 State House
Indianapolis, Indiana 46204
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FAX: (317) 233-3323

IOWA

Steven R. McCann
Division for Community Assistance
Iowa Department of Economic Development
200 East Grand Avenue
Des Moines, Iowa 50309
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FAX: (515) 242-4859

KENTUCKY

Ronald W. Cook
Office of the Governor
Department of Local Government
1024 Capitol Center Drive
Frankfort, Kentucky 40601-8204
Telephone: (502) 573-2382
FAX: (502) 573-2512

MAINE

Joyce Benson
State Planning Office
State House Station #38
Augusta, Maine 04333
Telephone: (207) 287-3261
FAX: (207) 287-6489

MARYLAND

William G. Carroll, Manager
State Clearinghouse for
Intergovernmental Assistance
Maryland Office of Planning
301 W. Preston Street - Room 1104
Baltimore, Maryland 21201-2365
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FAX: (410) 225-4480

MICHIGAN

Richard Pfaff
Southeast Michigan Council of Governments
1900 Edison Plaza
660 Plaza Drive
Detroit, Michigan 48226
Telephone: (313) 961-4266

Mississippi

Cathy Malette, Clearinghouse Officer
Department of Finance and Administration
455 North Lamar Street
Jackson, Mississippi 39202-3087
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FAX: (601) 359-6764

MISSOURI

Lois Pohl
Federal Assistance Clearinghouse
Office of Administration
P.O. Box 809
Room 760, Truman Building
Jefferson City, Missouri 65102
Telephone: (314) 751-4834
FAX: (314) 751-7819

NEVADA

Department of Administration
State Clearinghouse
Capitol Complex
Carson City, Nevada 89710
Telephone: (702) 687-4065
FAX: (702) 687-3983

NEW HAMPSHIRE

Jeffrey H. Taylor, Director
New Hampshire Office of State Planning
Attn: Intergovernmental Review Process, Mike Blake
2 1/2 Beacon Street
Concord, New Hampshire 03301
Telephone: (603) 271-2155
FAX: (603) 271-1728

NEW JERSEY

Gregory W. Adkins, Assistant Commissioner
New Jersey Department of Community Affairs

Please direct all correspondence and questions about intergovernmental review to:
Andrew J. Jaskolka, State Review Process
Intergovernmental Review Unit CN 800, Room 813A
Trenton, New Jersey 08625-0800
Telephone: (609) 292-9025
FAX: (609) 633-2132

NEW MEXICO

Robert Peters
State Budget Division
Room 190 Bataan Memorial Building
Santa Fe, New Mexico 87503
Telephone: (505) 827-3640

NEW YORK

New York State Clearinghouse
Division of the Budget
State Capitol
Albany, New York 12224
Telephone: (518) 474-1605

NORTH CAROLINA

Chrys Baggett, Director
N.C. State Clearinghouse
Office of the Secretary of Admin.
116 West Jones Street
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NORTH DAKOTA

North Dakota Single Point of Contact
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600 East Boulevard Avenue
Bismarck, North Dakota 58505-0170
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FAX: (701) 224-2308

OHIO

Larry Weaver
State Single Point of Contact
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Daniel W. Varin, Associate Director
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Please direct correspondence and questions to:
Review Coordinator
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SOUTH CAROLINA

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Tom Adams
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W. Virginia Development Office
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Charleston, West Virginia 25305
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WISCONSIN

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PUERTO RICO

Norma Burgos/Jose E. Caro
Chairwoman/Director
Puerto Rico Planning Board
Federal Proposals Review Office
Minillas Government Center
P.O. Box 41119
San Juan, Puerto Rico 00940-1119
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(809) 723-6190
FAX: (809) 724-3270
(809) 724-3103

NORTH MARIANA ISLANDS

State Single Point of Contact
Planning and Budget Office
Office of the Governor
Saipan, CM
Northern Mariana Islands 96950

VIRGIN ISLANDS

Jose George
Director, Office of Management and Budget
#41 Norregade Emancipation Garden Station
Second Floor
Saint Thomas, Virgin Islands 00802

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FAX: (809) 776-0069

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

2. DATE SUBMITTED		Applicant Identifier
3. DATE RECEIVED BY STATE		State Application Identifier
4. DATE RECEIVED BY FEDERAL AGENCY		Federal Identifier

1. TYPE OF SUBMISSION:

Application	*Preapplication*
☐ Construction	☐ Construction
☐ Non-Construction	☐ Non-Construction

5. APPLICANT INFORMATION

Legal Name:	**Organizational Unit:**
Address *(give city, county, state, and zip code)*:	Name and telephone number of the person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER (EIN):

		–							

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A.	State	H.	Independent School Dist.
B.	County	I.	State Controlled Institution of Higher Learning
C.	Municipal	J.	Private University
D.	Township	K.	Indian Tribe
E.	Interstate	L.	Individual
F.	Intermunicipal	M.	Profit Organization
G.	Special District	N.	Other *(Specify)*: _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other *(specify)*

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: | | | – | | | |

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(cities, counties, states, etc.)*:

13. PROPOSED PROJECT:

Start Date	Ending Date

14. CONGRESSIONAL DISTRICTS OF:

a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES, THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED STATE FOR REVIEW

17. IS APPLICATION DELINQUENT ON ANY FEDERAL DEBT?

☐ YES If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number

d. Signature of Authorized Representative	e. Date Signed

Previous Editions Not Usable

Standard Form 424 (Rev 4-88)
Prescribed by OMB Circular A-102

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item: Entry:

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Governments financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

Item: Entry:

12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory
14. List the applicant's Congressional District and District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

OMB Approval No. 0348-0044

BUDGET INFORMATION - Non-Construction Programs

SECTION A - BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$
2.						
3.						
4.						
5. TOTALS		$	$	$	$	$

SECTION B - BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (5)
	(1)	(2)	(3)	(4)	
a. Personnel	$	$	$	$	$
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges (sum of 6a - 6h)					
j. Indirect Charges					
k. TOTALS (sum of 6i and 6j)	$	$	$	$	$
7. Program Income	$	$	$	$	$

Standard Form 424A (4-88)
Prescribed by OMB Circular A-102

SECTION C - NON-FEDERAL RESOURCES

(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$
9.				
10.				
11.				
12. TOTALS (sum of lines 8 and 11)	$	$	$	$

SECTION D - FORECASTED CASH NEEDS

	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$	$	$	$	$
14. Non-Federal					
15. TOTAL (sum of lines 13 and 14)	$	$	$	$	$

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT

(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.	$	$	$	$
20. TOTALS (sum of lines 16 - 19)				

SECTION F - OTHER BUDGET INFORMATION

(Attach additional Sheets if Necessary)

21. Direct Charges:	22. Indirect Charges:
23. Remarks	

SF 424A (Rev 4-88) Page 2
Prescribed by OMB Circular A-102

INSTRUCTIONS FOR THE SF-424A

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a - k of Section B.

Section A. Budget Summary

Lines 1 - 4, Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the catalog program title and the catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in *Column* (a) and the respective catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1 - 4, Columns (c) through (g.)

For new applications, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

Lines 1 - 4, Columns (c) through (g.) (continued)

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in column (e) the amount of the increase or decrease of Federal Funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

Section B. Budget Categories

In the column heading (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1 - 4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Lines 6a-i - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1) - (4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

INSTRUCTIONS FOR THE SF-424A *(Continued)*

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal Resources

Lines 8 - 11 - Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.
Column (b) - Enter the contribution to be made by the applicant.
Column (c) - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.
Column (d) - Enter the amount of cash and in-kind contributions to be made from all other sources.
Column (e) - Enter totals of Columns (b), (c), and (d).

Line 12 - Enter the total for each of Columns (b) - (e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 - Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 - Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 - Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16 - 19 - Enter in Column (a) the same grant program titles shown in column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 - Enter the total for each of the Columns (b) - (e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 - Use this space to explain amounts for individual direct object-class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 - Provide any other explanations or comments deemed necessary.

OMB Approval No. 0348-0040

ASSURANCES -- NON-CONSTRUCTION PROGRAMS

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standard or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standard for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. §§ 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Title II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. § 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetland pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Costal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. §§ 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. § 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. §§ 469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. §§ 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

SF 424B (4-88) Back

TAB 5 ASSURANCES FORM-ATTACHMENT TO SF-424B

The applicant hereby assures and certifies compliance with all Federal statutes, regulations, policies, guidelines and requirements, including OMB Circular, Executive Order 12372, and Uniform Administrative Requirements for Grants and Cooperative Agreements - 24 CFR Part 85, that govern the application, acceptance and use of Federal funds for this federally-assisted project. Also the applicant assures and certifies that:

It has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.

It provided all information required by the NOFA to include certification and disclosures in accordance with the requirements of Section III of the NOFA.

It assessed its potential liability under State, local or tribal law, and that, upon being notified of a PHDEP grant award, will obtain adequate insurance coverage to protect itself against any potential liability out of the eligible activities under this program.

It understands that HUD may terminate funding if the applicant demonstrates an unwillingness or inability to : attain program goals; establish procedures that will minimize the time elapsing between cash advances and disbursements; adhere to grant agreement requirements or special conditions; avoid engaging in the improper award and administration of contracts; or submit reliable and timely reports.

It understands that the grant will be closeout in accordance with 24 CFR Part 85.50 and 24 CFR 761, and the FY 1997 PHDEP NOFA.

Signed this _____ day of _____ 1997

By:_____

(HOUSING AUTHORITY EXECUTIVE DIRECTOR)

Certification for a Drug-Free Workplace

U.S. Department of Housing and Urban Development
Office of Public and Indian Housing

OMB No. 2577-0044 (exp. 12/31/99)
OMB No. 2577-0157 (exp. 12/31/99)

This collection of information requires that each Housing Authority (HA) certify to the provisions of a drug-free workplace as a condition of assistance. Responses to the collection are required by the Drug-Free Workplace Act of 1988. The information requested does not lend itself to confidentiality.

HA Name:

Program/Activity Receiving Federal Grant Funding: (mark one)

☐ Operating Subsidy ☐ Sec.23 Leased Housing ☐ Development ☐ CIAP ☐ CGP ☐ HOPE VI ☐ Other (specify)

If Operating Subsidy or Section 23, enter the HA's FiscalYear Ending date in which funds are expected to be obligated :

If Development , CIAP, CGP, HOPE VI, or Other, enter the Federal Fiscal Year in which the funds are expected to be reserved :

Acting on behalf of the above named HA as its Authorized Official, I make the following certifications and agreements to the Department of Housing and Urban Development (HUD) regarding the sites listed below:

1. I certify that the above named HA will provide a drug-free workplace by:

   a. Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the HA's workplace and specifying the actions that will be taken against employees for violation of such prohibition.

   b. Establishing a drug-free awareness program to inform employees about the following:
      (1) The dangers of drug abuse in the workplace;
      (2) The HA's policy of maintaining a drug-free workplace;
      (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
      (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace.

   c. Making it a requirement that each employee of the HA be given a copy of the statement required by paragraph a.;

   d. Notifying the employee in the statement required by paragraph a. that, as a condition of employment with the HA, the employee will do the following:
      (1) Abide by the terms of the statement; and
      (2) Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;

   e. Notifying the HUD Field Office within ten days after receiving notice under subparagraph d. (2) from an employee or otherwise receiving actual notice of such conviction;

   f. Taking one of the following actions within 30 days of receiving notice under subparagraph d. (2) with respect to any employee who is so convicted:
      (1) Taking appropriate personnel action against such an employee, up to and including termination; or
      (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

   g. Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs a. thru f.

2. **Sites for Work Performance.** The HA shall list in the space provided below the site(s) for the performance of work done in connection with the HUD funding of the program/activity shown above: Place of Performance shall include the street address, city, county, State, and zip code. (If more space is needed, attach additional page(s) the same size as this form. Identify each sheet with the HA name and address and the program/activity receiving grant funding.)

I hereby certify that all the information stated herein, as well as any information provided in the accompaniment herewith, is true and accurate.
Warning: HUD will prosecute false claims and statements. Conviction may result in criminal and/or civil penalties. (18 U.S.C. 1001, 1010, 1012; 31 U.S.C. 3729, 3802)

Name, Title & Signature of Authorized HA Official & Date:

X

form **HUD-50070** (10/96)
ref. Handbooks 7417.1, 7475.13, 7485.1 & .3

CERTIFICATIONS AND ASSURANCES

AUTOMATED CAPABILITY

As an authorized representative of the applicant I certify that the program will include access to on-line computer/Internet capability as a means for the applicant to communicate with HUD on grant matters. I certify that if such access/capability does not exist at this time, that it will be operational within three months of HUD's transmittal of a Grant Agreement to the applicant organization, if the application is selected. (NOFA, VI (g) (9))

Signed this _____ day of _____, 1997

by:_____

PHA/IHA Executive Director or Other Authorized Representative

Applicant/Recipient Disclosure/Update Report

U.S. Department of Housing and Urban Development
Office of Ethics

OMB Approval No. 2510-0011 (exp. 3/31/98)

Instructions. (See Public Reporting Statement and Privacy Act Statement and detailed instructions on page 4.)

Part I Applicant/Recipient Information **Indicate whether this is an Initial Report** ☐ **or an Update Report** ☐

1. Applicant/Recipient Name, Address, and Phone (include area code)	Social Security Number or Employer ID Number

2. Project Assisted/ to be Assisted (Project/Activity name and/or number and its location by Street address, City, and State)

3. Assistance Requested/Received	4. HUD Program	5. Amount Requested/Received
		$

Part II. Threshold Determinations -- Applicants Only

1. Are you requesting HUD assistance for a specific project or activity, as provided by 24 CFR Part 12, Subpart C, **and** have you received, or can you reasonably expect to receive, an aggregate amount of all forms of covered assistance from HUD, States, and units of general local government, in excess of $200,000 during the Federal fiscal year (October 1 through September 30) in which the application is submitted? ☐ **Yes** ☐ **No**

   If Yes, you must complete the remainder of this report.

   If No, you must sign the certification below and answer the next question.

   I hereby certify that this information is true. (Signature) _____ Date _____

2. Is this application for a specific housing project that involves other government assistance? ☐ **Yes** ☐ **No**

   If Yes, you must complete the remainder of this report.

   If No, you must sign this certification.

   I hereby certify that this information is true. (Signature) _____ Date _____

If your answers to both questions are No, you do not need to complete Parts III, IV, or V, but you must sign the certification at the end of the report.

Part III. Other Government Assistance Provided/Requested

Department/State/Local Agency Name and Address	Program	Type of Assistance	Amount Requested/Provided

Is there other government assistance that is reportable in this Part and in Part V, but that is reported only in Part V? ☐ Yes ☐ No

If there is no other government assistance, you must certify that this information is true.

I hereby certify that this information is true. (Signature) _____ Date _____

form **HUD-2880** (3/92)
ref. Sec 102, HRA 1989; PL. 101 - 235

Part IV. Interested Parties

Alphabetical list of all persons with a reportable financial interest in the project or activity (for individuals, give the last name first)	Social Security Number or Employee ID Number	Type of Participation in Project/Activity	Financial Interest in Project/Activity ($ and %)

If there are no persons with a reportable financial interest, you must certify that this information is true.

I hereby certify that this information is true. (Signature) _____ Date _____

form **HUD-2880** (3/92)
ref. Sec 102, HRA 1989; PL. 101 - 235

Part V. Report on Expected Sources and Uses of Funds

Source

If there are no sources of funds, you must certify that this information is true.

I hereby certify that this information is true. (Signature) _____ Date _____

Use

If there are no uses of funds, you must certify that this information is true.

I hereby certify that this information is true. (Signature) _____ Date _____

Certification

Warning: If you knowingly make a false statement on this form, you may be subject to civil or criminal penalties under Section 1001 of Title 18 of the United States Code. In addition, any person who knowingly and materially violates any required disclosure of information, including intentional non-disclosure, is subject to civil money penalty not to exceed $10,000 for each violation.

I certify that this information is true and complete.

Signature	Date

form **HUD-2880** (3/92)
ref. Sec 102, HRA 1989; PL. 101 - 235

Public reporting burden for this collection of information is estimated to average 2.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Reports Management Officer, Paperwork Reduction Project (2510-0011), Office of Information Technology, U.S. Department of Housing and Urban Development, Washington, D.C. 20410-3600. This agency may not conduct or sponsor, and a person is not required to respond to, a collection information unless that collecton displays a valid OMB control number.

Do not send this form to the above address.

Privacy Act Statement. Except for Social Security Numbers (SSNs) and Employer Identification Numbers (EINs), the Department of Housing and Urban Development (HUD) is authorized to collect all the information required by this form under section 102 of the Department of Housing and Urban Development Reform Act of 1989, 42 U.S.C. 3531. Disclosure of SSNs and EINs is optional. The SSN or EIN is used as a unique identifier. The information you provide will enable HUD to carry out its responsibilities under Sections 102(b), (c), and (d) of the Department of Housing and Urban Development Reform Act of 1989, Pub. L. 101-235, approved December 15, 1989. These provisions will help ensure greater accountability and integrity in the provision of certain types of assistance administered by HUD. They will also help ensure that HUD assistance for a specific housing project under Section 102(d) is not more than is necessary to make the project feasible after taking account of other government assistance. HUD will make available to the public all applicant disclosure reports for five years in the case of applications for competitive assistance, and for generally three years in the case of other applications. Update reports will be made available along with the disclosure reports, but in no case for a period generally less than three years. All reports, both initial reports and update reports, will be made available in accordance with the Freedom of Information Act (5 U.S.C. §552) and HUD's implementing regulations at 24 CFR Part 15. HUD will use the information in evaluating individual assistance applications and in performing internal administrative analyses to assist in the management of specific HUD programs. The information will also be used in making the determination under Section 102(d) whether HUD assistance for a specific housing project is more than is necessary to make the project feasible after taking account of other government assistance. You must provide all the required information. Failure to provide any required information may delay the processing of your application, and may result in sanctions and penalties, including imposition of the administrative and civil money penalties specified under 24 CFR §12.34.

Note: This form only covers assistance made available by the Department. States and units of general local government that carry out responsibilities under Sections 102(b) and (c) of the Reform Act must develop their own procedures for complying with the Act.

Instructions (See Note 1 on last page.)

I. Overview. Subpart C of 24 CFR Part 12 provides for (1) initial reports from applicants for HUD assistance and (2) update reports from recipients of HUD assistance. An overview of these requirements follows.

A. Applicant disclosure (initial) reports: General. All applicants for assistance from HUD for a specific project or activity must make a number of disclosures, if the applicant meets a dollar threshold for the receipt of covered assistance during the fiscal year in which the application is submitted. The applicant must also make the disclosures if it requests assistance from HUD for a specific housing project that involves assistance from other governmental sources.

Applicants subject to Subpart C must make the following disclosures:

Assistance from other government sources in connection with the project,

The financial interests of persons in the project,

The sources of funds to be made available for the project, and

The uses to which the funds are to be put.

B. Update reports: General. All recipients of covered assistance must submit update reports to the Department to reflect substantial changes to the initial applicant disclosure reports.

C. Applicant disclosure reports: Specific guidance. The applicant must complete all parts of this disclosure form if **either** of the following **two** circumstances in paragraph 1. or 2., below, applies:

1.a. Nature of Assistance. The applicant submits an application for assistance for a specific project or activity (See Note 2) in which:

HUD makes assistance available to a recipient for a specific project or activity; or

HUD makes assistance available to an entity (other than a State or a unit of general local government), such as a public housing agency (PHA), for a specific project or activity, where the application is required by statute or regulation to be submitted to HUD for any purpose; **and**

b. Dollar Threshold. The applicant has received, or can reasonably expect to receive, an aggregate amount of all forms of assistance (See Note 3) from HUD, States, and units of general local government, in excess of $200,000 during the Federal fiscal year (October 1 through September 30) in which the application is submitted. (See Note 4)

2. The applicant submits an application for assistance for a specific housing project that involves other government assistance. (See Note 5) Note: There is no dollar threshold for this criterion: **any** other government assistance triggers the requirement. (See Note 6)

If the Application meets **neither** of these two criteria, the applicant need only complete Parts I and II of this report, as well as the certification at the end of the report. If the Application meets **either** of these criteria, the applicant must complete the entire report.

The applicant disclosure report must be submitted with the application for the assistance involved.

D. Update reports: Specific guidance. During the period in which an application for covered assistance is pending, or in which the assistance is being provided (as indicated in the relevant grant or other agreement), the applicant must make the following additional disclosures:

1. Any information that should have been disclosed in connection with the application, but that was omitted.

2. Any information that would have been subject to disclosure in connection with the application, but that arose at a later time, including information concerning an interested party that now meets the applicable disclosure threshold referred to in Part IV, below.

3. For changes in previously disclosed other government assistance:

For programs administered by the Assistant Secretary for Community Planning and Development, any change in other government assistance that exceeds the amount of such assistance that was previously disclosed by $250,000 or by 10 percent of the assistance (whichever is lower).

For all other programs, any change in other government assistance that exceeds the amount of such assistance that was previously disclosed.

4. For changes in previously disclosed financial interests, any change in the amount of the financial interest of a person that exceeds the amount of the previously disclosed interests by $50,000 or by 10 percent of such interests (whichever is lower).

5. For changes in previously disclosed sources or uses of funds:

a. For programs administered by the Assistant Secretary for Community Planning and Development:

Any change in a source of funds that exceeds the amount of all previously disclosed sources of funds by $250,000 or by 10 percent of those sources (whichever is lower); and

Any change in a use of funds under paragraph (b)(1)(iii) that exceeds the amount of all previously disclosed uses of funds by $250,000 or by 10 percent of those uses (whichever is lower).

b. For all programs, other than those administered by the Assistant Secretary for Community Planning and Development:

For projects receiving a tax credit under Federal, State, or local law, any change in a source of funds that was previously disclosed.

For all other projects, any change in a source of funds that exceeds the lower of:

The amount previously disclosed for that source of funds by $250,000, or by 10 percent of the amount previously disclosed for that source, whichever is lower; or

The amount previously disclosed for all sources of funds by $250,000, or by 10 percent of the amount previously disclosed for all sources of funds, whichever is lower.

c. For all programs, other than those administered by the Assistant Secretary for Community Planning and Development:

For projects receiving a tax credit under Federal, State, or local law, any change in a use of funds that was previously disclosed.

For all other projects, any change in a use of funds that exceeds the lower of:

The amount previously disclosed for that use of funds by $250,000, or by 10 percent of the amount previously disclosed for that use, whichever is lower; or

The amount previously disclosed for all uses of funds by $250,000, or by 10 percent of the amount previously disclosed for all uses of funds, whichever is lower.

Note: Update reports must be submitted within 30 days of the change requiring the update. The requirement to provide update reports only applies if the application for the underlying assistance was submitted on or after the effective date of Subpart C.

II. Line-by-Line Instructions.

A. Part I. Applicant/Recipient Information.

All applicants for HUD assistance specified in Section I.C.1.a., above, as well as all recipients required to submit an update report under Section I.D., above, must complete the information required by Part I. The applicant/recipient must indicate whether the disclosure is an initial or an update report. Line-by-line guidance for Part I follows:

1. Enter the full name, address, city, State, zip code, and telephone number (including area code) of the applicant/recipient. Where the applicant/recipient is an individual, the last name, first name, and middle initial must be entered. Entry of the applicant/recipient's SSN or EIN, as appropriate, is optional.

2. Applicants enter the name and full address of the project or activity for which the HUD assistance is sought. Recipients enter the name and full address of the HUD-assisted project or activity to which the update report relates. The most appropriate government identifying number must be used (e.g., RFP No.; IFB No.; grant announcement No.; or contract, grant, or loan No.) Include prefixes.

3. Applicants describe the HUD assistance referred to in Section I.C.1.a. that is being requested. Recipients describe the HUD assistance to which the update report relates.

4. Applicants enter the HUD program name under which the assistance is being requested. Recipients enter the HUD program name under which the assistance, that relates to the update report, was provided.

5. Applicants enter the amount of HUD assistance that is being requested. Recipients enter the amount of HUD assistance that has been provided and to which the update report relates. The amounts are those stated in the application or award documentation. NOTE: In the case of assistance that is provided pursuant to contract over a period of time (such as project-based assistance under section 8 of the United States Housing Act of 1937), the amount of assistance to be reported includes all amounts that are to be provided over the term of the contract, irrespective of when they are to be received.

Note: In the case of Mortgage Insurance under 24 CFR Subtitle B, Chapter II, the mortgagor is responsible for making the applicant disclosures, and the mortgagee is responsible for furnishing the mortgagor's disclosures to the Department. Update reports must be submitted directly to HUD by the mortgagor.

Note: In the case of the Project-Based Certificate program under 24 CFR Part 882, Subpart G, the owner is responsible for making the applicant disclosures, and the PHA is responsible for furnishing the owner's disclosures to HUD. Update reports must be submitted through the PHA by the owner.

B. Part II. Threshold Determinations — Applicants Only

Part II contains information to help the applicant determine whether the remainder of the form must be completed. **Recipients filing Update Reports should not complete this Part.**

1. The first question asks whether the applicant meets the Nature of Assistance and Dollar Threshold requirements set forth in Section I.C.1. above.

If the answer is Yes, the applicant must complete the remainder of the form. If the answer is No, the form asks the applicant to certify that its response is correct, and to complete the next question.

2. The second question asks whether the application is for a specific housing project that involves other government assistance, as described in Section I.C.2. above.

If the answer is Yes, the applicant must complete the remainder of the form. If the answer is No, the form asks the applicant to certify that its response is correct.

If the answer to both questions1 and 2 is No, the applicant need not complete Parts III, IV, or V of the report, but must sign the certification at the end of the form.

C. Part III. Other Government Assistance.

This Part is to be completed by both applicants filing applicant disclosure reports and recipients filing update reports. Applicants must report any other government assistance involved in the project or activity for which assistance is sought. Recipients must report any other government assistance involved in the project or activity, to the extent required under Section I.D.1., 2., or 3., above.

Other government assistance is defined in note 5 on the last page. For purposes of this definition, other government assistance is expected to be made available if, based on an assessment of all the circumstances involved, there are reasonable grounds to anticipate that the assistance will be forthcoming.

Both applicant and recipient disclosures must include all other government assistance involved with the HUD assistance, as well as any other government assistance that was made available before the request, but that has continuing vitality at the time of the request. Examples of this latter category include tax credits that provide for a number of years of tax benefits, and grant assistance that continues to benefit the project at the time of the assistance request.

The following information must be provided:

1. Enter the name and address, city, State, and zip code of the government agency making the assistance available. Include at least one organizational level below the agency name. For example, U.S. Department of Transportation, U.S. Coast Guard; Department of Safety, Highway Patrol.

2. Enter the program name and any relevant identifying numbers, or other means of identification, for the other government assistance.

3. State the type of other government assistance (e.g., loan, grant, loan insurance).

4. Enter the dollar amount of the other government assistance that is, or is expected to be, made available with respect to the project or activities for which the HUD assistance is sought (applicants) or has been provided (recipients).

If the applicant has no other government assistance to disclose, it must certify that this assertion is correct.

To avoid duplication, if there is other government assistance under this Part and Part V, the applicant/recipient should check the appropriate box in this Part and list the information in Part V, clearly designating which sources are other government assistance.

D. Part IV. Interested Parties.

This Part is to be completed by both applicants filing applicant disclosure reports and recipients filing update reports.

Applicants must provide information on:

(1) All developers, contractors, or consultants involved in the application for the assistance or in the planning, development, or implementation of the project or activity and

(2) any other person who has a financial interest in the project or activity for which the assistance is sought that exceeds $50,000 or 10 percent of the assistance (whichever is lower).

Recipients must make the additional disclosures refferred to in Section I.D.1.,2., or 4, above.

Note: A financial interest means any financial involvement in the project or activity, including (but not limited to) situations in which an individual or entity has an equity interest in the project or activity, shares in any profit on resale or any distribution of surplus cash or other assets of the project or activity, or receives compensation for any goods or services provided in connection with the project or activity. Residency of an individual in housing for which assistance is being sought is not, by itself, considered a covered financial interest.

The information required below must be provided.

1. Enter the full names and addresses of all persons referred to in paragraph (1) or (2) of this Part. If the person is an entity, the listing must include the full name of each officer, director, and principal stockholder of the entity. All names must be listed alphabetically, and the names of individuals must be shown with their last names first.

2. Entry of the Social Security Number (SSN) or Employee Identification Number (EIN), as appropriate, for each person listed is optional.

3. Enter the type of participation in the project or activity for each person listed: i.e., the person's specific role in the project (e.g., contractor, consultant, planner, investor).

4. Enter the financial interest in the project or activity for each person listed. The interest must be expressed both as a dollar amount and as a percentage of the amount of the HUD assistance involved.

If the applicant has no persons with financial interests to disclose, it must certify that this assertion is correct.

5. Part V. Report on Sources and Uses of Funds. This Part is to be completed by both applicants filing applicant disclosure reports and recipients filing update reports.

The applicant disclosure report must specify all expected sources of funds — both from HUD and from any other source — that have been, or are to be, made available for the project or activity. Non-HUD sources of funds typically include (but are not limited to) other government assistance referred to in Part III, equity, and amounts from foundations and private contributions. The report must also specify all expected uses to which funds are to be put. All sources and uses of funds must be listed, if, based on an assessment of all the circumstances involved, there are reasonable grounds to anticipate that the source or use will be forthcoming.

Note that if any of the source/use information required by this report has been provided elsewhere in this application package, the applicant need not repeat the information, but need only refer to the form and location to incorporate it into this report. (It is likely that some of the information required by this report has been provided on SF 424A, and on various budget forms accompanying the application.) If this report requires information beyond that provided elsewhere in the application package, the applicant must include in this report all the additional information required.

Recipients must submit an update report for any change in previously disclosed sources and uses of funds as provided in Section I.D.5., above.

General Instructions — sources of funds

Each reportable source of funds must indicate:

a. The name and address, city, State, and zip code of the individual or entity making the assistance available. At least one organizational level below the agency name should be included. For example, U.S. Department of Transportation, U.S. Coast Guard; Department of Safety, Highway Patrol.

b. The program name and any relevant identifying numbers, or other means of identification, for the assistance.

c. The type of assistance (e.g., loan, grant, loan insurance).

Specific instructions — sources of funds.

(1) For programs administered by the Assistant Secretaries for Fair Housing and Equal Opportunity and Policy Development and Research, each source of funds must indicate the total amount of approved, and received; and must be listed in descending order according to the amount indicated.

(2) For programs administered by the Assistant Secretaries for Housing-Federal Housing Commissioner, Community Planning and Development, and Public and Indian Housing, each source of funds must indicate the total amount of funds involved, and must be listed in descending order according to the amount indicated.

(3) If Tax Credits are involved, the report must indicate all syndication proceeds and equity involved.

General instructions—uses of funds.

Each reportable use of funds must clearly identify the purpose to which they are to be put. Reasonable aggregations may be used, such as "total structure" to include a number of structural costs, such as roof, evevators, exterior masonry, etc.

Specific instructions -- uses of funds.

(1) For programs administered by the Assistant Secretaries for Fair Housing and Equal Opportunity and Policy Development and Research, each use of funds must indicate the total amount of funds involved; must be broken down by amount committed, budgeted, and planned; and must be listed in descending order according to the amount indicated.

form HUD-2880 (3/92)
ref. Sec 102, HRA 1989; PL. 101 - 235

(ii) For programs administered by the Assistant Secretaries for Housing-Federal Housing Commissioner, Community Planning and Development, and Public and Indian Housing, each use of funds must indicate the total amount of funds involved and must be listed in descending order according to the amount involved.

(iii) If any program administered by the Assistant Secretary for Housing-Federal Housing Commissioner is involved, the report must indicate all uses paid from HUD sources and other sources, including syndication proceeds. Uses paid should include the following amounts.

AMPO
Architect's fee — design
Architect's fee — supervision
Bond premium
Builder's general overhead
Builder's profit
Construction interest
Consultant fee
Contingency Reserve
Cost certification audit fee
FHA examination fee
FHA inspection fee
FHA MIP
Financing fee
FNMA / GNMA fee
General requirements
Insurance
Legal — construction
Legal — organization
Other fees
Purchase price
Supplemental management fund
Taxes
Title and recording
Operating deficit reserve
Resident initiative fund
Syndication expenses
Working capital reserve
Total land improvement
Total structures

Uses paid from syndication must include the following amounts:

Additional acquisition price and expenses
Bridge loan interest
Development fee
Operating deficit reserve
Resident initiative fund
Syndication expenses
Working capital reserve

Footnotes:

1. All citations are to 24 CFR Part 12, which was published in the Federal Register on March 14, 1991 at 56 Fed. Reg. 11032.
2. A list of the covered assistance programs can be found at 24 CFR §12.30, or in the rules or administrative instructions governing the program involved. Note: The list of covered programs will be updated perodically.
3. Assistance means any contract, grant, loan, cooperative agreement, or other form of assistance, including the insurance or guarantee of a loan or mortgage, that is provided with respect to a specific project or activity under a program administered by the Department. The term does not include contracts, such as procurements contracts, that are subject to the Federal Acquisition Regulation (FAR) (48 CFR Chapter 1).
4. See 24 CFR §§12.32 (a)(2) and (3) for detailed guidance on how the threshold is calculated.
5. "Other government assistance" is defined to include any loan, grant, guarantee, insurance, payment, rebate, subsidy, credit, tax benefit, or any other form of direct or indirect assistance from the Federal government (other than that requested from HUD in the application), a State, or a unit of general local government, or any agency or instrumentality thereof, that is, or is expected to be made, available with respect to the project or activities for which the assistance is sought.
6. For further guidance on this criterion, and for a list of covered programs, see 24 CFR §12.50.
7. For purposes of Part 12, a person means an individual (including a consultant, lobbyist, or lawyer); corporation; company; association; authority; firm; partnership; society; State, unit of general local government, or other government entity, or agency thereof (including a public housing agency); Indian tribe; and any other organization or group of people.

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:	2. Status of Federal Action	3. Report Type:
☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	☐ a. bid/offer/application b. initial award c. post-award	☐ a. initial filing b. material change **For Material Change Only:** Year _____ Quarter _____ date of last report _____

4. Name and Address of Reporting Entity: ☐ Prime ☐ Subawardee Tier _____, *if known:* **Congressional District,** *if known:*	5. **If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime:** **Congressional District,** *if known:*
6. **Federal Department/Agency:**	7. **Federal Program Name/Description:** **CFDA Number,** *if applicable:* _____
8. **Federal Action Number,** *if known:*	9. **Award Amount,** *if known:* $
10. a. **Name and Address of Lobbying Entity** *(if individual, last name, first name, MI):*	b. **Individuals Performing Services** *(including address of different from No. 10a.)* *(last name, first name, MI):*

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

11. Amount of Payment *(check all that apply) :* $ _____ ☐ actual ☐ planned 12. Form of Payment *(check all that apply):* ☐ a. cash ☐ b. in-kind; specify: nature _____ value _____	13. Type of Payment *(check all that apply):* ☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____

14. **Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment indicated in Item 11.:**

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. **Continuation Sheet(s) SF-LLL-A attached:** ☐ Yes ☐ No

16. **Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.**	**Signature:** _____ **Print Name:** _____ **Title:** _____ **Telephone No.:** _____ **Date:** _____

Federal Use Only:	Authorized for Local Reproduction Standard Form - LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. Section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 [e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency]. Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.
    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If "other," specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Approved by OMB
0348-0046

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Reporting Entity: _____ **Page** _____ **of** _____

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TAB 11G APPLICANT'S ANTI-LOBBYING CERTIFICATION

Each applicant must sign either the Certification Regarding Lobbying or the Standard Form-LLL, Disclosure of Lobbying Activities and include it in the application as Exhibit 21. Section 319 of Public Law 101-121 prohibits recipients of Federal contracts, grants, and loans from using appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government. A common rule governing the restrictions on lobbying was published as an interim rule on February 26, 1990 (55 FR 6736) and supplemented by a Notice published June 15, 1990 (55 FR 24540). The rule requires applicants for and recipients of assistance exceeding $100,000 to certify that no Federal Funds have been or will be spend on lobbying activities in connection with the assistance. The rule also requires disclosures from applicants and recipients if nonappropriated funds have been spent or committed for lobbying activities if those activities would be prohibited if paid with appropriated funds. The law provides substantial monetary penalties for failure to file the required certification or disclosure. This does not apply to Indian tribes of IHAs, tribal organizations, or any other Indian organization with respect to expenditures specifically permitted by other Federal law that are not covered by the definition of person in 24 CFR Part 87.

Attached are the appropriate certification and the Standard Form-LLL.

CERTIFICATION FOR CONTRACTS, GRANTS, LOANS AND COOPERATION AGREEMENTS

The undersigned certifies, to the best of his or her knowledge and belief that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of the Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering in to of any cooperative agreement, and the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee or any agency, a Member of Congress, an officer or employee of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered int. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Executed this _____ day of _____, 199_____

BY _____
Signature

_____
(Typed or Printed Name)

_____
(Title, if any)

TAB 10H DEBARMENT AND SUSPENSION CERTIFICATION

By signing and submitting this proposal, the applicant, defined as the primary recipient in accordance with 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal Department or agency.

(b) have not within a 3-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property.

(c) are not presently indicted or for otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (b) of this certification; and

(d) have not within a 3-year period preceding this application/proposal had one or more public transactions (Federal, state, or local) terminated for cause or default.

The applicant agrees that by submitting this proposal, it will include without modification the clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion - Lower Tier Covered Transactions" i.e. with subgrantees or contractors, in all lower tier covered transactions and in all solicitations for lower tier covered transactions in accordance with 45 CFR Part 76.

Should the applicant not be able to provide this certification, an explanation as to why should be placed after the assurances page in the application package.

Signed this _____ day of _____, 199___

by:_____

Print Name & Title:

_____

CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE

Public Law 103-227, Part C - Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees shall certify accordingly.

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988: 45 CFR Part 76, Subpart, F. Sections 76.630(c) and (d)(2) and 76.645(a)(1) and (b) provide that a Federal agency may designate a central receipt point for STATE-WIDE AND STATE AGENCY-WIDE certifications, and for notification of criminal drug convictions. For the Department of Health and Human Services, the central pint is: Division of Grants Management and Oversight, Office of Management and Acquisition, Department of Health and Human Services, Room 517-D, 200 Independence Avenue, SW Washington, DC 20201.

Certification Regarding Drug-Free Workplace Requirements
(Instructions for Certification)

1. By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.
2. The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.
3. For grantees other than individuals, Alternate I applies.
4. For grantees who are individuals, Alternate II applies.
5. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.
6. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios). 7. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).
8. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15);

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All direct charge employees; (ii) All indirect charge employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) Temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

Certification Regarding Drug-Free Workplace Requirements

Alternate I. (Grantees Other Than Individuals)

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about --

(1)The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace; (3) Any available drug

counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will --

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted --

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

(B) The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

_____

_____

Check ☐ if there are workplaces on file that are not identified here.

Alternate II. (Grantees Who Are Individuals)

(a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

(b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

[55 FR 21690, 21702, May 25, 1990]

[FR Doc. 97–19917 Filed 7–24–97; 1:06 pm]
BILLING CODE 4210–33–C

Federal Register

Tuesday
July 29, 1997

Part V

Department of Labor

Pension and Welfare Benefits Administration

29 CFR Part 2570

Final Rule Relating to Adjustment of Civil Monetary Penalties

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2570

RIN 1210–0056

Final Rule Relating to Adjustment of Civil Monetary Penalties

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: This document contains a final rule that adjusts the civil monetary penalties under Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA), pursuant to the requirements of the Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Act), as amended by the Debt Collection Improvement Act of 1996 (the Act). The Act amended the 1990 Act to require generally the adjustment of civil monetary penalties for inflation no later than 180 days after enactment of the Act, and at least once every four years thereafter, in accordance with guidelines specified in the 1990 Act, as amended.

DATES: This final rule is effective on July 29, 1997. This final rule applies only to violations occurring after July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Rudy Nuissl, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, (202) 219–7461. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Section 3720E of the Act (Pub. L. 104–134, 110 Stat. 1321–373) amended section 4 of the 1990 Act (Pub. L. 101–410, 104 Stat. 890) to require, with certain exceptions, that, by a regulation published in the **Federal Register,** each civil monetary penalty (CMP) be adjusted in accordance with guidelines specified in the amendment. The Act specifies that any such increase in a CMP shall apply only to violations which occur after the date the increase takes effect. On April 18, 1997, the Department published a notice of proposed rulemaking in the **Federal Register** at 62 FR 19078 (the ''proposal'') containing proposed regulations that would adjust the CMPs under Title I of ERISA pursuant to the 1990 Act, as amended by the Act. No comments were received from the public in response to the proposal, and the Department is by this notice promulgating the regulations as set forth in the proposal adjusting the CMPs under sections 209(b)(1), 502(c)(1), 502(c)(2) and 502(c)(3) of ERISA (29 U.S.C. 1059(b)(1), 1132(c)(1), 1132(c)(2) and 1132(c)(3)).

The term ''civil monetary penalty'' is defined in the 1990 Act to mean any penalty, fine or other sanction that—

(A)(i) is for a specific monetary amount as provided by Federal law; or

(ii) has a maximum amount provided for by Federal law; and

(B) is assessed or enforced by an agency pursuant to Federal law; and

(C) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

Only CMPs that are specified by statute or regulation in dollar amounts are adjusted under the 1990 Act, as amended. CMPs that are specified as percentages are not adjusted. The statutory citations for each of the CMPs under Title I of ERISA that are adjusted by the final rule contained in this Notice are set forth in columns (A) and (B) of Table A. Column (C) briefly describes the nature of the violations associated with these citations. Column (D) of Table A indicates the dollar amount of each CMP to be adjusted, and Column (E) sets forth the year that each penalty was established by law or last adjusted. Columns (F), (G), (H), (I), and (J) contain the intermediate results of applying the series of steps mandated by the 1990 Act, as amended. Reference should be made to Column (K) of Table A to determine the dollar amounts of the adjusted penalties that are effected by the final rule contained in this document pursuant to the requirements of the 1990 Act, as amended.

TABLE A.—INFLATION ADJUSTMENT OF CIVIL MONETARY PENALTIES UNDER TITLE I OF ERISA

(A) U.S. Code citation	(B) ERISA Title I section	(C) Nature of violation	(D) Penalty amount to be adjusted	(E) Year penalty last set or adjusted	(F) CLA factor=456.7/CPI below	(G) Penalty after raw adjustment=col D×456.7/col F	(H) Unrounded penalty increase=col G − col D	(I) Rounded penalty increase	(J) Uncapped maximum penalty=col D+col I	(K) Capped penalty=min(col J, 1.1×col D)
29 U.S.C. 1059(b)	209(b)	Failure to furnish or maintain records.	$10 per employee.	1974	146.9	$31.09	$21.09	$20	$30	$11 per employee.
29 U.S.C. 1132(c)(1)(A) ..	502(c)(1)(A)	Failure to notify plan participants of group health benefits under COBRA.	Up to $100 a day.	1986	327.9	139.28	39.28	40	140	Up to $110 a day.
		Failure to notify participants and beneficiaries re: asset transfer.	Up to $100 a day.	1990	389.1	117.37	17.37	20	120	Up to $110 a day.
29 U.S.C. 1132(c)(1)(B) ..	502(c)(1)(B)	Refusal to provide required info in timely manner.	Up to $100 a day.	1974	146.9	310.89	210.89	210	310	Up to $110 a day.
29 U.S.C. 1132(c)(2)	502(c)(2)	Failure or refusal to file an annual report.	Up to $100 a day.	1987	340.1	1,342.84	342.84	300	1,300	Up to $1,100 a day.
29 U.S.C. 1132(c)(3)	502(c)(3)	Failure to notify participants and beneficiaries re: failure to meet minimum funding requirements.	Up to $100 a day.	1989	371.7	122.87	22.87	20	120	Up to $110 a day.
		Failure to notify certain persons re: transfer of excess pension assets to health account.	Up to $100 a day.	1990	389.1	117.37	17.37	20	120	Up to $110 a day.

Specifically, the 1990 Act, as amended, provides that the required inflation adjustment shall be determined by increasing the maximum CMP amount or the range of maximum and minimum CMP amounts, as applicable, for each CMP by a cost-of-living adjustment (CLA). The term ''cost-of-living adjustment'' is defined in the Act as the percentage for each CMP by which the Consumer Price Index (CPI) for the month of June of the calendar year preceding the adjustment exceeds the CPI for the month of June of the calendar year in which the amount of such CMP was last set or adjusted by law. The term ''Consumer Price Index'' is defined in the 1990 Act, as amended, to mean the Consumer Price Index for All-Urban Consumers published by the U.S. Department of Labor.

Accordingly, to calculate the CLA it is necessary to divide the CPI for June of the calendar year preceding the adjustment by the CPI for June of the calendar year in which the CMP was last set by law or adjusted for inflation. (See Column (F) of Table A). In order to calculate the raw inflation adjustment, it is necessary to multiply the original penalty amount by the relevant CLA. (See Column (G) of Table A). The subtraction of the original CMP amount from this product yields the unrounded penalty increase (See Column (H) of Table A).

Section 5 of the 1990 Act, as amended, sets out the manner in which inflation adjustments must be rounded. Specifically, any increase in the maximum CMP or the range of maximum and minimum CMPs, as applicable, must be rounded to the nearest:

(1) Multiple of $10.00 in the case of penalties less than or equal to $100;

(2) Multiple of $100.00 in the case of penalties greater than $100 but less than or equal to $1000;

(3) Multiple of $1000 in the case of penalties greater than $1000 but less than or equal to $10,000;

(4) Multiple of $10,000 in the case of penalties greater than $100,000 but less than or equal to $200,000; or

(5) multiple of $25,000 in the case of penalties greater than $200,000.

Once the penalty increase has been rounded in accordance with the procedures set forth in the 1990 Act, as amended (see Column (I) of Table A), the rounded increase must be added to the original penalty amount to determine the uncapped maximum penalty. (See Column (J) of Table A). The first adjustment of a CMP pursuant to the amendment effected by the Act, however, may not exceed 10% of the penalty being adjusted. The final adjusted penalty amounts listed in Column (K) of Table A reflect the application of this statutory cap.

Applying the CLA rules described above, the following CMPs under Title I of ERISA are being adjusted.[1] (See Columns (A), (B), and (C) of Table A):

(1) the per capita CMP of $10.00 set by ERISA section 209(b) (29 U.S.C. 1059(b)) for a failure to furnish the employee benefit plan information or to maintain the plan records specified in ERISA section 209(a);

(2) the CMP of up to $100.00 a day (as determined in the discretion of a court) set by section 502(c)(1)(A) (29 U.S.C. 1132(c)(1)(A)) for a failure or refusal by a plan administrator to meet the requirements of ERISA section 101(e)(1) (29 U.S.C. 1021(e)(1)) (concerning notice with regard to a transfer or excess pension assets) or ERISA section 606(4) (29 U.S.C. 1166(4)) (concerning notice with regard to the occurrence of qualifying events), or to comply with a request for information which such administrator is required by Title I of ERISA to furnish to a participant or beneficiary;

(3) the CMP of up to $100.00 a day (as determined the discretion of a court) set by ERISA section 502(c)(1)(B) (29 U.S.C. 1132(c)(1)(B)) for a failure or refusal to comply with a request for information which a plan administrator is required by Title I of ERISA to furnish a participant or beneficiary;

(4) the CMP of up to $1,000.00 a day set by ERISA section 502(c)(2) (29 U.S.C. 1132(c)(2)) for the failure on the part of a plan administrator to file the annual report required to be filed under ERISA section 101(b)(4) (29 U.S.C. 1021(b)(4));

(5) the CMP of up to $100.00 a day (as determined in the discretion of a court) set by ERISA section 502(c)(3) (29 U.S.C. 1132(c)(3)) for the failure on the part of an employer to meet the requirements of ERISA section 101(d) (29 U.S.C. 1021(d)); (concerning provision of notice to participants and beneficiaries for failure to meet the minimum funding requirements) or ERISA section 101(3)(2) (29 U.S.C. 1021(e)(2)) (concerning provision of notice regarding transfers of excess pension assets).

The final rule contained in this document amends Part 2570 (''Procedural Regulations Under the Employee Retirement Income Security Act'') of Title 29 of the *Code of Federal Regulations* (CFR) by adding a new ''Subpart E—Adjustment of Civil Penalties Under ERISA Title I.'' New Subpart E contains five new regulations effecting the adjustment for inflation of the civil monetary penalties discussed above.

[1] Civil penalty set forth in ERISA section 502(c)(4) for a failure to provide the information specified in ERISA section 101(f), relating to Medicare and Medicaid coverage data bank requirements, is not being implemented or enforced. See H.R. Conf. Rep. No. 103–733, 103rd Cong. 2nd Sess., at 22 (1994).

Executive Order 12866

The Department has determined that this regulatory action is not a ''significant rule'' within the meaning of Executive Order 12866 concerning federal regulations, because it is not likely to result in: (1) An annual effect on the economy of $100 million or more, or an adverse and material effect on a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) the creation of a serious inconsistency or interference with an action taken or planned by another agency; (3) a material alteration in the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) the raising of novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Regulatory Flexibility Act

When a Federal agency promulgates a final rule under 5 U.S.C. 553 after being required to publish a proposed rule, the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires the agency to perform a final regulatory flexibility analysis unless the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Small entities include small businesses, organizations, and governmental jurisdictions. In conjunction with the publication of the notice of proposed rulemaking on April 18, 1997 (62 FR 19078), the undersigned certified that the rule, if promulgated as proposed, would not have a significant effect on a substantial number of small entities.

Because the final rule is identical to the proposed rule and because no comments were received from the public in response to the April 18, 1997, notice of proposed rulemaking, there is no basis for modification of the determination that the rule will not have a significant impact on a substantial number of small entities. Accordingly, the Department is not required to conduct a final regulatory flexibility analysis.

Paperwork Reduction Act

This final rule contains no information collection requirements which are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3500 et seq.).

Unfunded Mandates Reform Act

For purposes of Title II of the Unfunded Mandates Reform Act of 1995, 5 U.S.C. 1531–1538, as well as Executive Order 12875, this final rule does not contain any federal mandate that may result in increased expenditures in either Federal, State, local, and tribal governments in the aggregate, or impose an annual burden exceeding $100 million on the private sector.

Congressional Review

The Department has determined that this final rule is not a ''major rule'' as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Statutory Authority

This final regulation is adopted pursuant to authority contained in section 4 of the Federal Civil Penalties Adjustment Act of 1990, Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996, Pub. L. 104–134, Title III, section 31001(s)(1), 110 Stat. 1321–373, and contained in sections 209(b), 502(c)(1) and 505 of ERISA, 29 U.S.C. 1059(b), 1132(c)(1) and 1135.

List of Subjects in 29 CFR Part 2570

Administrative practice and procedure, Employee benefit plans, Employee Retirement Income Security Act, Penalties, Pensions.

Final Rule

In view of the foregoing, Part 2570 of Chapter XXV of Title 29 of the Code of Federal Regulations is amended as set forth below:

PART 2570—PROCEDURAL REGULATIONS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT

1. The authority citation for Part 2570 is revised to read as follows:

Authority: 5 U.S.C. 8477(c)(3); 29 U.S.C. 1108, 1135; Reorganization Plan No. 4 of 1978; 5 U.S.C. 8477(c)(3); Secretary of Labor Order No. 1–87.

Subpart A is also issued under 29 U.S.C. 1132(c)(1).

Subpart E is also issued under sec. 4, Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note), as amended by sec. 31001(s)(1), Pub. L. 104–134, 110 Stat. 1321–373.

2. Part 2570 is amended by adding a new Subpart E to read as follows:

Subpart E—Adjustment of Civil Penalties Under ERISA Title I

Sec.

Subpart E—Adjustment of Civil Penalties Under ERISA Title I

§ 2570.100 In general.

Section 3720E of the Debt Collection Improvement Act of 1996 (the Act, Pub. L. 104–134, 110 Stat. 1321–373) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Act, Pub. L. 101–410, 104 Stat. 890) to require generally that the head of each federal agency adjust the civil monetary penalties subject to its jurisdiction for inflation within 180 days after enactment of the Act and at lease once every four years thereafter.

§ 2570.209b–1 Adjusted civil penalty under section 209(b).

In accordance with the requirements of the 1990 Act, as amended, the amount of the civil monetary penalty established by section 209(b) of the Employee Retirement Income Security Act of 1974, as amended (ERISA), is hereby increased from $10 for each employee to $11 for each employee. This adjusted penalty applies only to violations occurring after July 29, 1997.

§ 2570.502c–1 Adjusted civil penalty under section 502(c)(1).

In accordance with the requirements of the 1990 Act, as amended, the maximum amount of the civil monetary penalty established by section 502(c)(1) of the Employee Retirement Income Security Act of 1974, as amended (ERISA), is hereby increased from $100 a day to $110 a day. This adjusted penalty applies only to violations occurring after July 29, 1997.

§ 2570.502c–2 Adjusted civil penalty under section 502(c)(2).

In accordance with the requirements of the 1990 Act, as amended, the maximum amount of the civil monetary penalty established by section 502(c)(2) of the Employee Retirement Income Security Act of 1974, as amended (ERISA), is hereby increased from $1000 a day to $1100 a day. This adjusted penalty applies only to violations occurring after July 29, 1997.

§ 2570.502c–3 Adjusted civil penalty under section 502(c)(3).

In accordance with the requirements of the 1990 Act, as amended, the maximum amount of the civil monetary penalty established by section 502(c)(3) of the Employee Retirement Income Security Act of 1974, as amended (ERISA), is hereby increased from $100 a day to $110 a day. This adjusted penalty applies only to violations occurring after July 29, 1997.

Signed at Washington, DC this 22nd day of July 1997.

Olena Berg,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 97–19769 Filed 7–28–97; 8:45 am]

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Part VI

Department of Transportation

Federal Aviation Administration

14 CFR Part 25

Revised Structural Loads Requirements for Transport Category Airplanes; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. 28312; Amdt. No. 25–91]

RIN 2120–AF70

Revised Structural Loads Requirements for Transport Category Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment revises the structural loads design requirements of the Federal Aviation Regulations (FAR) for transport category airplanes by incorporating changes developed in cooperation with the Joint Aviation Authorities (JAA) of Europe and the Aviation Rulemaking Advisory Committee (ARAC). This action makes some of the requirements more rational and eliminates differences between current U.S. and European requirements that impose unnecessary costs on airplane manufacturers. These changes are intended to achieve common airworthiness standards and language between the requirements of the U.S. regulations and the Joint Aviation Requirements (JAR) of Europe while maintaining at least the level of safety provided by the current regulations and industry practices.

EFFECTIVE DATE: August 28, 1997.

FOR FURTHER INFORMATION CONTACT: James Haynes, Airframe and Propulsion Branch, ANM–112, Transport Airplane Directorate, Aircraft Certification Service, FAA, 1601 Lind Avenue, SW., Renton, WA 98055–4056; telephone (206) 227–2131.

SUPPLEMENTARY INFORMATION:

Background

The manufacturing, marketing and certification of transport airplanes is increasingly an international endeavor. In order for U.S. manufacturers to export transport airplanes to other countries the airplane must be designed to comply, not only with the U.S. airworthiness requirements for transport airplanes (14 CFR part 25), but also with the transport airworthiness requirements of the countries to which the airplane is to be exported, unless the importing country accepts the aircraft without findings of compliance with specified regulations.

The European countries have developed a common airworthiness code for transport category airplanes that is administered by the JAA. This code is the result of a European effort to harmonize the various airworthiness codes of the European countries and is called the Joint Aviation Requirements (JAR)–25. It was developed in a format similar to 14 CFR part 25. Many other countries have airworthiness codes that are aligned closely to part 25 or to JAR–25, or they use these codes directly for their own certification purposes.

Although JAR–25 is very similar to part 25, there are differences in methodologies and criteria that often result in the need to address the same design objective with more than one kind of analysis or test in order to satisfy both part 25 and JAR airworthiness codes. These differences result in additional costs to the transport airplane manufacturers and additional costs to the U.S. and foreign authorities that must continue to monitor compliance with different airworthiness codes.

In 1988, the FAA, in cooperation with the JAA and other organizations representing the U.S. and European aerospace industries, began a process to harmonize the airworthiness requirements of the United States and the European authorities. The objective was to achieve common requirements for the certification of transport category airplanes without a substantive change in the level of safety provided by the regulations and industry practices. Other airworthiness authorities such as Transport Canada have also participated in this process.

In 1992, the harmonization effort was undertaken by the Aviation Rulemaking Advisory Committee (ARAC). A working group of industry and government structural loads specialists of Europe, the United States, and Canada was chartered by notice in the **Federal Register** (58 FR 13819, March 15, 1993) to harmonize the design loads sections of Subpart C of part 25. The bulk of the harmonization tasks for Subpart C were completed by the working group and recommendations were submitted to FAA by letter dated February 2, 1995. The FAA concurred with the recommendations and proposed them in Notice of Proposed Rulemaking (NPRM) No. 95–14; which was published in the **Federal Register** on August 29, 1995 (60 FR 44998).

In establishing a design requirement for the nose gear, its attaching structure and the forward fuselage structure, § 25.499(e) continues to require consideration of positioning the nose gear in any steerable position. The term ''any'' is continued from the current regulation. The term, and the requirements of the section, are understood in the engineering and regulated communities to require demonstration that the nose gear and associated structures will sustain the applicable loads throughout the full range of nose gear positions.

Discussion of Comments

Comments were received from transport airplane manufacturers, industry associations and foreign airworthiness authorities. All of the commenters express support for the proposals in Notice No. 95–14 although a few make some recommendations for changes. One comment believes the changes proposed for § 25.415 could be a burden to some applicants with airplanes that are derived from models that were certified to earlier amendment levels of the FAR and JAR. To provide relief for these derivative airplanes, the commenter proposes a change to paragraph (b) of § 25.415 which would allow the use of ''realistic'' aerodynamic hinge moment coefficients for control surfaces in lieu of the prescribed coefficients of paragraph (b). The FAA does not agree that there is likely to be a burden for derivative airplanes since the proposed rule applies to new designs. In addition, the design gust speed does not create an increased requirement over existing design requirements. Part 24 and JAR–25 were identical in using 88 feet per second (about 52 knots) in defining hinge moment for ground gust conditions. However, JAR § 25.519 prescribes a 65 knot wind speed for ground gusts during jacking and tie-down, and specifically requires application of those gusts to control surfaces. As a result, aircraft designs already have to meet the 65 knot rather than the 52 knot requirement. The ARAC recommends, with FAA and JAA concurrence, that ground gusts on control surfaces be addressed in just one section, § 25.415, so Notice No. 95–14 proposes to revise this section to achieve the same effect as the § 25.519 of JAR–25 by incorporating the 65-knot wind speed into § 25.415. The net effect is that there is no change in the ground gust speed requirement for control surfaces over that already required by JAR–25.

Furthermore, the use of rational aerodynamic hinge moment coefficients would necessitate a rational ground gust speed as well, and the 65 knot design gust speed is not necessarily a rational design speed for ground gusts. Jet blasts in airport operations and normal storm conditions often exceed 65 knots but service history has shown that the 65 knot design speed when combined with the conservative prescribed hinge moments of paragraph (b) provides a satisfactory design.

One commenter recommends that the formulation of the requirement for hinge moments in § 25.415 be changed to show the 65 knot wind speed explicitly rather than embedding this value into the multiplying constant. The FAA agrees that this has merit since the connection between the 65 knot wind speed of §§ 25.415 and 25.519 could otherwise be missed in any future rulemaking actions. The rule is adopted with a change to show the 65 knot wind speed explicitly in the formula for control surface hinge moments.

One commenter points out that the proposed revision to paragraph (a) of § 25.481 references paragraphs 25.479(c)(1) and (2) for vertical and drag load conditions and that these latter paragraphs, as proposed, no longer specify those conditions. Notice 95–14 proposes to express the substance of § 25.479(c)(1) and (2) in more general terms in § 25.473(c). The commenter is correct. The rule is adopted with a change to delete the incorrect references.

Regulatory Evaluation Summaries

Regulatory Evaluation, Regulatory Flexibility Determination, and Trade Impact Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic effect of regulatory changes on small entities. Third, the Office of Management and Budget directs agencies to assess the effects of regulatory changes on international trade. In conducting these analyses, the FAA has determined that this rule:

(1) Will generate benefits that justify its costs and is not a ''significant regulatory action'' as defined in the Executive Order; (2) is not significant as defined in DOT's Regulatory Policies and Procedures; (3) will not have a significant impact on a substantial number of small entities; and (4) will not constitute a barrier to international trade. These analyses, available in the docket, are summarized below.

Regulatory Evaluation Summary

Depending on airplane design, the rule could result in additional compliance costs for some manufacturers. If manufacturers choose to design to and justify a V_D–V_C magin of 0.05 Mach, there will be an increase in analysis costs of approximately $145,000 per certification. The requirement in § 25.473 to consider structural flexibility in the analysis of landing loads and the increase in the factor on the maximum static reaction on the nose gear vertical force in § 25.499 could add compliance costs, but the FAA estimates that these will be negligible.

The rule will also result in cost savings. Revisions in the conditions in which unchecked pitch maneuvers are investigated could reduce certification costs by as much as $10,000 per certification. The FAA estimates that the change in the speed margin between V_B and V_C from a fixed margin to a margin variable with altitude could result in substantial, though unquantified, cost savings to some manufacturers. Manufacturers that design small transport category airplanes with direct mechanical rudder control systems could realize a savings as a result of the modification in the rudder control force limit in § 25.351. No comments were received on the costs or cost savings resulting from these changes.

The primary benefit of the rule will be the cost savings associated with harmonization of the FAR with the JAR. In order to sell airplanes in a global marketplace, manufacturers usually certify their products under the FAR and the JAR. The cost savings from reducing the resources necessary to demonstrate compliance with non-harmonized design load requirements will outweigh any incremental costs of the rule, resulting in a net cost savings. These savings will be realized by U.S. manufacturers that market airplanes in JAA countries as well as by manufacturers in JAA countries that market airplanes in the U.S.

The change to § 25.335(b)(2) in the minimum speed margin for atmospheric conditions from 0.05 Mach to 0.07 Mach could produce safety benefits. The increase in the margin between V_D/M_D and V_C/M_C is more conservative and will standardize training across international lines. Crews could cross-train and cross-fly and this standardization will enhance safety as well as result in more efficient training.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily and disproportionally burdened by Federal regulations. The RFA requires a Regulatory Flexibility Analysis if a proposed or final rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. FAA Order 2100.14A, Regulatory Flexibility Criteria and Guidance, establishes threshold cost values and small entity standards for complying with RFA review requirements in FAA rulemaking actions. The Order defines ''small entities'' in terms of size threshold, ''significant economic impact'' in terms of annualized cost thresholds, and ''substantial number'' as a number which is not less than eleven and which is more than one-third of the small entities subject to the proposed or final rule.

Order 2100.14A specifies a size threshold for classification as a small manufacturer as 75 or fewer employees. Since none of the manufacturers affected by this rule has 75 or fewer employees and any costs of the rule will be negligible, the rule will not have a significant economic impact on a substantial number of small manufacturers.

International Trade Impact Assessment

The rule will not constitute a barrier to international trade, including the export of U.S. airplanes to foreign markets and the import of foreign airplanes into the U.S. Because the rule will harmonize with the JAR, it would, in fact, lessen restraints on trade.

Federalism Implications

The regulations amended herein do not have a substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Thus, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) standards and recommended practices to the maximum extent practicable. The FAA has determined that this rule does not conflict with any international agreement of the United States.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96–511), there are no requirements for information collection associated with this rule.

Conclusion

Because these changes to the structural loads requirements do not result in any substantial economic costs, the FAA has determined that this rule will not be significant under Executive Order 12866. Because there has not been significant public interest in this issue, the FAA has determined that this action is not significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 25, 1979). In addition, since there are no small entities affected by this rulemaking, the FAA certifies that the rule will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act, since none will be affected. A copy of the regulatory evaluation prepared for this project may be examined in the Rules Docket or obtained from the person identified under the caption **FOR FURTHER INFORMATION CONTACT**.

List of Subjects in 14 CFR Part 25

Air transportation, Aircraft, Aviation safety, Safety.

The Amendments

Accordingly, the Federal Aviation Administration (FAA) amends 14 CFR part 25 of the Federal Aviation Regulations as follows:

PART 25—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY AIRPLANES

1. The authority citation for part 25 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

2. Section 25.331 is amended by revising the introductory text of paragraph (c) and paragraph (c)(1) to read as follows:

§ 25.331 Symmetric maneuvering conditions.

* * * * *

(c) *Pitch maneuver conditions.* The conditions specified in paragraphs (c)(1) and (2) of this section must be investigated. The movement of the pitch control surfaces may be adjusted to take into account limitations imposed by the maximum pilot effort specified by § 25.397(b), control system stops and any indirect effect imposed by limitations in the output side of the control system (for example, stalling torque or maximum rate obtainable by a power control system.)

(1) *Maximum pitch control displacement at V_A.* The airplane is assumed to be flying in steady level flight (point A_1, § 25.333(b)) and the cockpit pitch control is suddenly moved to obtain extreme nose up pitching acceleration. In defining the tail load, the response of the airplane must be taken into account. Airplane loads that occur subsequent to the time when normal acceleration at the c.g. exceeds the positive limit maneuvering load factor (at point A_2 in § 25.333(b)), or the resulting tailplane normal load reaches its maximum, whichever occurs first, need not be considered.

* * * * *

3. Section 25.335 is amended by revising paragraphs (a)(2) and (b)(2) to read as follows:

§ 25.335 Design airspeeds.

* * * * *

(a) * * *

(2) Except as provided in § 25.335(d)(2), V_C may not be less than $V_B + 1.32\ U_{REF}$ (with U_{REF} as specified in § 25.341(a)(5)(i)). However V_C need not exceed the maximum speed in level flight at maximum continuous power for the corresponding altitude.

* * * * *

(b) * * *

(2) The minimum speed margin must be enough to provide for atmospheric variations (such as horizontal gusts, and penetration of jet streams and cold fronts) and for instrument errors and airframe production variations. These factors may be considered on a probability basis. The margin at altitude where M_C is limited by compressibility effects must not less than 0.07M unless a lower margin is determined using a rational analysis that includes the effects of any automatic systems. In any case, the margin may not be reduced to less than 0.05M.

* * * * *

4. Section 25.345 is amended by revising paragraph (d) to read as follows:

§ 25.345 High lift devices.

* * * * *

(d) The airplane must be designed for a maneuvering load factor of 1.5 g at the maximum take-off weight with the wing-flaps and similar high lift devices in the landing configurations.

5. Section 25.351 is revised to read as follows:

§ 25.351 Yaw maneuver conditions.

The airplane must be designed for loads resulting from the yaw maneuver conditions specified in paragraphs (a) through (d) of this section at speeds from V_{MC} to V_D. Unbalanced aerodynamic moments about the center of gravity must be reacted in a rational or conservative manner considering the airplane inertia forces. In computing the tail loads the yawing velocity may be assumed to be zero.

(a) With the airplane in unaccelerated flight at zero yaw, it is assumed that the cockpit rudder control is suddenly displaced to achieve the resulting rudder deflection, as limited by:

(1) The control system on control surface stops; or

(2) A limit pilot force of 300 pounds from V_{MC} to V_A and 200 pounds from V_C/M_C to V_D/M_D, with a linear variation between V_A and V_C/M_C.

(b) With the cockpit rudder control deflected so as always to maintain the maximum rudder deflection available within the limitations specified in paragraph (a) of this section, it is assumed that the airplane yaws to the overswing sideslip angle.

(c) With the airplane yawed to the static equilibrium sideslip angle, it is assumed that the cockpit rudder control is held so as to achieve the maximum rudder deflection available within the limitations specified in paragraph (a) of this section.

(d) With the airplane yawed to the static equilibrium sideslip angle of paragraph (c) of this section, it is assumed that the cockpit rudder control is suddenly returned to neutral.

6. Section 25.363 is amended by revising the heading and paragraph (a) to read as follows:

§ 25.363 Side load on engine and auxiliary power unit mounts.

(a) Each engine and auxiliary power unit mount and its supporting structure must be designed for a limit load factor in lateral direction, for the side load on the engine and auxiliary power unit mount, at least equal to the maximum load factor obtained in the yawing conditions but not less than—

(1) 1.33; or

(2) One-third of the limit load factor for flight condition A as prescribed in § 25.333(b).

* * * * *

7. Section 25.371 is revised to read as follows:

§ 25.371 Gyroscopic loads.

The structure supporting any engine or auxiliary power unit must be designed for the loads including the gyroscopic loads arising from the conditions specified in §§ 25.331, 25.341(a), 25.349, 25.351, 25.473, 25.479, and 25.481, with the engine or auxiliary power unit at the maximum rpm appropriate to the condition. For the purposes of compliance with this section, the pitch maneuver in § 25.331(c)(1) must be carried out until the positive limit maneuvering load factor (point A_2 in § 25.333(b)) is reached.

8. Section 25.415 is amended by revising paragraph (a)(2) to read as follows:

§ 25.415 Ground gust conditions.

(a) * * *

(2) The control system stops nearest the surfaces, the control system locks, and the parts of the systems (if any) between these stops and locks and the control surface horns, must be designed for limit hinge moments H, in foot pounds, obtained from the formula, $H=.0034KV^2cS$, where—

V=65 (wind speed in knots)
K=limit hinge moment factor for ground gusts derived in paragraph (b) of this section.
c=mean chord of the control surface aft of the hinge line (ft);
S=area of the control surface aft of the hinge line (sq ft);

* * * * *

9. Section 25.473 is revised to read as follows:

§ 25.473 Landing load conditions and assumptions.

(a) For the landing conditions specified in § 25.479 to § 25.485 the airplane is assumed to contact the ground—

(1) In the attitudes defined in § 25.479 and § 25.481;

(2) With a limit descent velocity of 10 fps at the design landing weight (the maximum weight for landing conditions at maximum descent velocity); and

(3) With a limit descent velocity of 6 fps at the design take-off weight (the maximum weight for landing conditions at a reduced descent velocity).

(4) The prescribed descent velocities may be modified if it is shown that the airplane has design features that make it impossible to develop these velocities.

(b) Airplane lift, not exceeding airplane weight, may be assumed unless the presence of systems or procedures significantly affects the lift.

(c) The method of analysis of airplane and landing gear loads must take into account at least the following elements:

(1) Landing gear dynamic characteristics.

(2) Spin-up and springback.

(3) Rigid body response.

(4) Structural dynamic response of the airframe, if significant.

(d) The limit inertia load factors corresponding to the required limit descent velocities must be validated by tests as defined in § 25.723(a)

(e) The coefficient of friction between the tires and the ground may be established by considering the effects of skidding velocity and tire pressure. However, this coefficient of friction need not be more than 0.8.

10. Section 25.479 is revised to read as follows:

§ 25.479 Level landing conditions.

(a) In the level attitude, the airplane is assumed to contact the ground at forward velocity components, ranging from V_{L1} to 1.25 V_{L2} parallel to the ground under the conditions prescribed in § 25.473 with—

(1) V_{L1} equal to V_{S0} (TAS) at the appropriate landing weight and in standard sea level conditions; and

(2) V_{L2} equal to V_{S0} (TAS) at the appropriate landing weight and altitudes in a hot day temperature of 41 degrees F. above standard.

(3) The effects of increased contact speed must be investigated if approval of downwind landings exceeding 10 knots is requested.

(b) For the level landing attitude for airplanes with tail wheels, the conditions specified in this section must be investigated with the airplane horizontal reference line horizontal in accordance with Figure 2 of Appendix A of this part.

(c) For the level landing attitude for airplanes with nose wheels, shown in Figure 2 of Appendix A of this part, the conditions specified in this section must be investigated assuming the following attitudes:

(1) An attitude in which the main wheels are assumed to contact the ground with the nose wheel just clear of the ground; and

(2) If reasonably attainable at the specified descent and forward velocities, an attitude in which the nose and main wheels are assumed to contact the ground simultaneously.

(d) In addition to the loading conditions prescribed in paragraph (a) of this section, but with maximum vertical ground reactions calculated from paragraph (a), the following apply:

(1) The landing gear and directly affected attaching structure must be designed for the maximum vertical ground reaction combined with an aft acting drag component of not less than 25% of this maximum vertical ground reaction.

(2) The most severe combination of loads that are likely to arise during a lateral drift landing must be taken into account. In absence of a more rational analysis of this condition, the following must be investigated:

(i) A vertical load equal to 75% of the maximum ground reaction of § 25.473 must be considered in combination with a drag and side load of 40% and 35% respectively of that vertical load.

(ii) The shock absorber and tire deflections must be assumed to be 75% of the deflection corresponding to the maximum ground reaction of § 25.473(a)(2). This load case need not be considered in combination with flat tires.

(3) The combination of vertical and drag components is considered to be acting at the wheel axle centerline.

11. Section 25.481 is amended by revising paragraph (a) introductory text and by designating the undesignated text following paragraph (a)(2) as paragraph (a)(3) and revising it to read as follows:

§ 25.481 Tail down landing conditions.

(a) In the tail-down attitude, the airplane is assumed to contact the ground at forward velocity components, ranging from V_{L1} to V_{L2} parallel to the ground under the conditions prescribed in § 25.473 with—

(1) * * *

(2) * * *

(3) The combination of vertical and drag components is considered to be acting at the main wheel axle centerline.

* * * * *

12. Section 25.483 is amended by revising the heading, introductory text, and paragraph (a) to read as follows:

§ 25.483 One-gear landing conditions.

For the one-gear landing conditions, the airplane is assumed to be in the level attitude and to contact the ground on one main landing gear, in accordance with Figure 4 of Appendix A of this part. In this attitude—

(a) The ground reactions must be the same as those obtained on that side under § 25.479(d)(1), and

* * * * *

13. Section 25.485 is amended by adding the introductory text to read as follows:

§ 25.485 Side load conditions.

In addition to § 25.479(d)(2) the following conditions must be considered:

* * * * *

14. Section 25.491 is revised to read as follows:

§ 25.491 Taxi, takeoff and landing roll.

Within the range of appropriate ground speeds and approved weights, the airplane structure and landing gear are assumed to be subjected to loads not less than those obtained when the aircraft is operating over the roughest ground that may reasonably be expected in normal operation.

15. Section 25.499 is amended by revising the heading and paragraph (e) to read as follows:

§ 25.499 Nose-wheel yaw and steering.

* * * * *

(e) With the airplane at design ramp weight, and the nose gear in any steerable position, the combined application of full normal steering torque and vertical force equal to 1.33 times the maximum static reaction on the nose gear must be considered in designing the nose gear, its attaching structure, and the forward fuselage structure.

16. Section 25.561 is amended by revising paragraph (c) to read as follows:

§ 25.561 General.

* * * * *

(c) For equipment, cargo in the passenger compartments and any other large masses, the following apply:

(1) Except as provided in paragraph (c)(2) of this section, these items must be positioned so that if they break loose they will be unlikely to:

(i) Cause direct injury to occupants;

(ii) Penetrate fuel tanks or lines or cause fire or explosion hazard by damage to adjacent systems; or

(iii) Nullify any of the escape facilities provided for use after an emergency landing.

(2) When such positioning is not practical (e.g. fuselage mounted engines or auxiliary power units) each such item of mass shall be restrained under all loads up to those specified in paragraph (b)(3) of this section. The local attachments for these items should be designed to withstand 1.33 times the specified loads if these items are subject to severe wear and tear through frequent removal (e.g. quick change interior items).

* * * * *

Issued in Washington D.C. on July 14, 1997.

Barry L. Valentine,

Acting Administrator.

[FR Doc. 97–19040 Filed 7–28–97; 8:45 am]

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Federal Register

Tuesday
July 29, 1997

Part VII

Environmental Protection Agency

40 CFR Part 258

Revisions to Criteria for Municipal Solid Waste Landfills; Final Rule and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[F–97–FLXF–FFFFF; FRL–5865–3]

RIN 2050–AE24

Revisions to Criteria for Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Land Disposal Program Flexibility Act of 1996 (LDPFA) directed the Administrator of the U.S. Environmental Protection Agency (EPA) to provide additional flexibility to Approved States for any landfill that receives 20 tons or less of municipal solid waste per day. The additional flexibility applies to alternative frequencies of daily cover, frequencies of methane monitoring, infiltration layers for final cover, and means for demonstrating financial assurance. The additional flexibility will allow the owners and operators of small municipal solid waste landfills (MSWLFs) the opportunity to reduce their costs of MSWLF operation while still protecting human health and the environment. This direct final rule recognizes, as did Congress in enacting the LDPFA, that these decisions are best made at the State and local level and, therefore, offers this flexibility to approved States.

In the proposed rules Section of today's **Federal Register**, EPA is concurrently proposing and soliciting comment on this rule. If adverse comments are received, EPA will withdraw this direct final rule and address the comments in a subsequent final rule. EPA will not provide additional opportunity for comment.

DATES: This final action will become effective on October 27, 1997 unless EPA receives adverse comment by August 28, 1997. If such adverse comment is received, EPA will withdraw this direct final rule by publishing timely notice in the **Federal Register**.

ADDRESSES: Supporting materials are available for viewing in the RCRA Information Center (RIC), located at Crystal Gateway I, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The Docket Identification Number is F–97–FLXF–FFFFF. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling 703 603–9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page. The index and some supporting materials are available electronically. See the ''Supplementary Information'' section for information on accessing them.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at 800 424–9346 or TDD 800 553–7672 (hearing impaired). In the Washington, DC, metropolitan area, call 703 412–9810 or TDD 703 412–3323.

For more detailed information on specific aspects of this rulemaking, contact Mr. Allen J. Geswein, U.S. Environmental Protection Agency, Office of Solid Waste (5306W), 401 M Street, SW, Washington, D.C. 20460, 703 308–7261, [GESWEIN.ALLEN@EPAMAIL. EPA.GOV].

SUPPLEMENTARY INFORMATION: The index and the following supporting materials are available on the Internet:

Memorandum to: RCRA Docket
From: Allen J. Geswein, Environmental Engineer
Subject: Daily Cover Requirements for MSWLFs
Memorandum to: RCRA Docket
From: Allen J. Geswein, Environmental Engineer
Subject: Landfill Gas Monitoring Requirements for MSWLFs
Memorandum to: RCRA Docket
From: Allen J. Geswein, Environmental Engineer
Subject: Infiltration Layer Requirements for MSWLFs
Memorandum to: RCRA Docket
From: Allen J. Geswein, Environmental Engineer
Subject: Financial Assurance Requirements for MSWLFs

Follow these instructions to access the information electronically:

WWW: http://www.epa.gov/epaoswer/nonhazardous waste
FTP: ftp.epa/gov
Login: anonymous
Password: your Internet address

Files are located in /pub/gopher/OSWRCRA.

Regulated Entities

Entities potentially regulated by this action are public or private owners or operators of municipal solid waste landfills (MSWLFs) that dispose 20 tons or less of municipal solid waste daily, based on an annual average. Regulated categories and entities include the following.

Category	Examples of regulated entities
Industry	Owners or operators of small MSWLFs.
Municipal Governments	Owners or operators of small MSWLFs.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities EPA is now aware could potentially be impacted by today's action. It is possible that other types of entities not listed in the table could also be affected. To determine whether your facility would be impacted by this action, you should carefully examine the applicability criteria in the proposal. If you have questions regarding the applicability of this action to a particular facility, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Preamble Outline

I. Authority

The Agency is promulgating these regulations under the authority of sections 1008(a)(3), 2002(a), 4004(a), and 4010(c) of the Resource

Conservation and Recovery Act (RCRA), as amended, 42 USC 6907(a)(3), 6912(a), 6944(a), and 6949a(c).

II. Background

When EPA promulgated the Revised Criteria for Municipal Solid Waste Landfills on October 9, 1991 (56 FR 50978), the Agency included an exemption for owners and operators of certain small municipal solid waste landfills (MSWLF) units from the Design Criteria (Subpart D) and Ground-Water Monitoring and Corrective Action (Subpart E) requirements of the criteria. To qualify for the exemption, the small landfill could only accept twenty tons or less of municipal solid waste per day (based on an annual average), have no evidence of existing ground-water contamination, and either: (1) Serve a community that experiences an annual interruption of at least three consecutive months of surface transportation that prevents access to a regional waste management facility, or (2) be located in an area that annually receives less than or equal to 25 inches of precipitation and serves a community that has no practicable waste management alternative. In adopting this limited exemption, the Agency believed it had complied with the statutory requirement to protect human health and the environment, taking into account the practicable capabilities of small landfill owners and operators.

In January 1992, the Sierra Club and the Natural Resources Defense Council (NRDC) filed a petition with the U.S. Court of Appeals, District of Columbia Circuit, for review of the Subtitle D Criteria. On May 7, 1993, the Court of Appeals determined in *Sierra Club* v. *United States Environmental Protection Agency*, 992 F.2d 337 (D.C. Cir. 1993) that under RCRA section 4010(c), the only factor EPA could consider in determining whether facilities must monitor groundwater was whether such monitoring was ''necessary to detect contamination,'' not whether such monitoring is ''practicable.'' Thus, the Court vacated the small landfill exemption as it pertained to ground-water monitoring, and remanded that portion of the final rule to the Agency for further consideration.

Consequently, as part of the Agency's October 1, 1993 final rule (58 FR 51536; October 1, 1993), EPA rescinded the exemption from ground-water monitoring for qualifying small MSWLFs. Also at that time, EPA delayed the effective date of the MSWLF criteria for qualifying small MSWLFs for two years (until October 9, 1995) to allow owners and operators of such small MSWLFs adequate time to decide whether to continue to operate in light of the Court's ruling, and to prepare financially for the added costs if they decided to continue to operate.

On October 6, 1995, EPA issued a final rule extending the general compliance date of the MSWLF criteria for two years, from October 9, 1995 to October 9, 1997, for qualifying small MSWLFs. The purpose of the extension was to allow Approved States time to determine alternative ground-water monitoring requirements for qualifying small MSWLFs. This means that qualifying small MSWLFs are not subject to the requirements of 40 CFR part 258 until October 9, 1997, so long as the MSWLF continues to qualify for the small landfill exemption in 40 CFR 258.1(f)(1). Should a MSWLF no longer meet the conditions of § 258.1(f)(1), that landfill must comply with all of the requirements of 40 CFR part 258, including the design and ground-water monitoring requirements. Until October 9, 1997, owners and operators of qualifying small MSWLFs are subject to the requirements of 40 CFR part 257, Subpart A. Because owners and operators of qualifying small MSWLFs may be subject to more stringent State requirements, these owners and operators are encouraged to work with their respective State programs to understand the regulatory requirements for their facilities.

On March 26, 1996, the President signed the ''Land Disposal Program Flexibility Act'' (LDPFA), Public Law 104–119, which among other things, reinstated the exemption from ground-water monitoring for qualifying small MSWLFs. EPA has issued a final rule reinstating the exemption (61 FR 50410; September 25, 1996).

The law also directed the Agency to issue rules that grant the Director of an Approved State the flexibility to establish alternative requirements for all MSWLFs that receive 20 tons or less of municipal solid waste per day, based on an annual average. **The additional flexibility is not limited to small MSWLFs in dry or remote locations; rather, the alternative requirements may be applied to any MSWLF receiving 20 tons or less of municipal solid waste as determined by the Director of an Approved State.** Specifically, the LDPFA directed EPA to promulgate revisions to existing criteria which would allow an approved State to establish for small MSWLFs alternative frequencies of daily cover application, frequencies of methane gas monitoring, infiltration layers for final cover, and means for demonstrating financial assurance. These alternative requirements are to take into account climatic and hydrogeologic conditions and are to be protective of human health and the environment. There is no provision in the LDPFA that directed the Agency to extend the exemption from ground-water monitoring to other than qualifying small MSWLFs; therefore, the exemption from ground-water monitoring will continue to apply only to small MSWLFs in either dry or remote areas. For the reasons set forth in a prior notice, EPA has no plans to extend this exemption to all small MSWLFs (56 FR 50989, October 9, 1991).

III. Summary of the Direct Final Rule

This direct final rule amends the Revised Criteria for Municipal Solid Waste Landfills to allow the Director of an Approved State the ability to grant additional flexibility to small MSWLFs for alternative frequencies of daily cover, alternative frequencies of methane monitoring, and alternative infiltration layers for final cover. When providing this flexibility, the State Director must consider, after public review and comment, the unique characteristics of small communities and take into account climatic and hydrogeologic conditions while ensuring that any alternative requirements are protective of human health and the environment.

The amendments contained in today's direct final rule may be applied by the Director of Approved States to all MSWLFs receiving 20 tons or less of municipal solid waste per day, based on an annual average, as appropriate.

In the proposed rules Section of today's **Federal Register**, EPA is proposing this identical rule and soliciting public comment. If adverse comments are received, EPA will withdraw this direct final rule and address the comments in a subsequent final rule. EPA will not provide additional opportunity for comment.

IV. Description of Direct Final Rule

The purpose of this direct final rule is to allow the Director of an Approved State to establish alternative requirements to certain provisions of the Revised Criteria for Municipal Solid Waste Landfills for small MSWLFs, provided the Director determines that the alternative requirements are protective of human health and the environment.

A. Daily Cover

Section 258.21 currently requires owners or operators to cover disposed solid waste at the end of each operating day, or more frequently if necessary, with six inches of earthen material.

Alternative materials of an alternative thickness may be used when approved by the Director of an Approved State if the owner or operator demonstrates that the alternative material and thickness control disease vectors, fires, odors, blowing litter, scavenging without presenting a threat to human health and the environment. The use of daily cover to control disease vectors, fires, odors, blowing litter, and scavenging has been a requirement of Federal regulations applicable to MSWLFs for nearly twenty years (40 CFR 257.3–6(a) and (c)(4)). At least 45 States have had this requirement for ten or more years.

While the owner or operator is required to place cover on waste at the end of each operating day, the owner or operator can reduce the cost of daily cover by limiting the number of days per week that waste is accepted. If the facility accepts waste for disposal two days per week, then daily cover is required on those two operating days and not on the other days of the week. While § 258.21(c) allows a temporary waiver of daily cover during extreme seasonal climatic conditions, the current rules do not allow the State to substantially alter the requirement that cover be applied on a daily basis.

Consistent with the LDPFA, to provide additional flexibility to Approved States, this rule contains a provision that allows the Director of an Approved State, after public review and comment, to establish alternative frequencies for daily cover for small MSWLFs provided that the Director takes into account climatic and hydrogeologic conditions and determines that the alternative requirements are protective of human health and the environment.

B. Methane Gas Monitoring

The decomposition of municipal solid waste produces methane, an explosive gas. Section 258.23 requires quarterly monitoring for methane gas to control the possibility of an explosion and does not afford the opportunity for the Director of an Approved State to allow monitoring on a less frequent basis. The current rule further requires that if the methane levels exceed the allowable levels, a danger of an explosion may exist, and the Subtitle D Criteria establish the actions that must be taken to control the explosion potential. These allowable levels are based on safety considerations and are derived from allowable concentrations of methane contained in mining regulations. EPA estimates that monitoring can cost less than $100 per quarter.

However, consistent with the LDPFA, this rule contains a provision that allows the Director of an Approved State to establish alternative frequencies of methane monitoring for any small MSWLFs provided that the Director, after public review and comment, takes into account climatic and hydrogeologic conditions and determines that the alternative requirements are protective of human health and the environment.

C. Final Cover and Discussion of Performance Standard in § 258.60(a)(1)

1. Additional Flexibility

Section 258.60(a) establishes a two-part performance standard for final cover of MSWLFs. The final cover must keep the closed facility as dry as possible by reducing infiltration and performs the added function of minimizing maintenance by reducing erosion. Sections 258.60(a) (1) through (3) indicate the types of layers that are known to provide appropriate control. Section 258.60(b) allows the Director of an Approved State to approve alternative designs that provide an equivalent reduction in infiltration and an equivalent protection from wind and water erosion.

The purpose of the performance standard is to reduce the possibility of the ''bathtub effect'' which can lead to ground-water contamination. The ''bathtub effect'' occurs when more liquid enters the MSWLF than escapes causing the MSWLF to fill with liquid. As the unit fills with liquid, more leachate is formed, the hydraulic head in the MSWLF increases, causing the leachate to migrate to groundwater.

The Agency is aware that there may have been misunderstandings regarding the performance standard in § 258.60(a)(1) which addresses the permeability of the final cover system. The most common misconception is that this provision dictates that in all cases the infiltration barrier **must** include a flexible membrane if the landfill contains a flexible membrane liner (FML) or if the permeability of the soil underlying the landfill is comparable to the permeability of an FML. This may not necessarily be true. The Agency believes that in certain site-specific situations it may be possible to construct an infiltration layer that achieves an equivalent reduction in infiltration without matching the permeability in the liner material.

In selecting the alternative infiltration barrier that achieves an equivalent reduction in infiltration, the Director of an Approved State may base the decision on mathematical models (e.g., EPA's Hydrologic Evaluation of Landfill Performance (HELP)) or can utilize mass water balance calculations. The design of a final cover system that minimizes run-on and maximizes factors such as run-off, lateral drainage within the cover system, water storage capacity in the cover, and the ability of the vegetative layer to utilize water may meet the performance standard (''have a permeability less than or equal to the permeability of any bottom liner system'') without the need for a flexible membrane. In making this decision, it may be feasible that the Director of the Approved State could establish an alternative infiltration layer requirement that would be applicable Statewide for MSWLFs or could make the decision on a site-specific basis for individual MSWLFs.

The LDPFA requires that EPA provide additional flexibilities to the Director of Approved States regarding final cover design than that afforded by the current regulations at § 258.60(a)(1). Thus, consistent with the LDPFA, in order to provide this additional flexibility to Approved States, today's rule contains a provision that allows the Director of an Approved State to establish alternative infiltration barriers in the final cover for any small MSWLFs provided that the Director, after public review and comment, takes into account climatic and hydrogeologic conditions and determines that the alternative requirements are protective of human health and the environment.

2. Applicability to ''Qualifying Small MSWLFs'' That Close

In extending the effective date for qualifying small MSWLFs in dry or remote locations, EPA amended section 258.1(d) to exempt such small MSWLFs which stop receiving waste before October 9, 1997 from having to comply with Part 258 requirements except for the final cover requirements in § 258.60(a) [60 FR 52337; October 6, 1995]. Such a qualifying MSWLF would have to complete the final cover requirements within one year (60 FR 52337; October 6, 1995). During the course of developing this direct final rule, a question arose as to whether such a qualifying small MSWLF in a dry or remote location which stops receiving waste prior to the effective date of October 9, 1997 may utilize an alternative final cover design authorized by the Director of an Approved State, including an alternative final cover design for the infiltration layer being addressed in today's rule. This question arose because the language in § 258.1(d)(1) requiring qualifying small MSWLFs to comply with final cover requirements only refers to the requirements under § 258.60(a) which sets forth a federal cover design.

Despite referring only to the federal final cover design standard, EPA intended to provide maximum flexibility in complying with the revised criteria to owners or operators of MSWLFs located in States with approved programs (56 FR 50992; Oct. 9, 1991). This intent extended to allowing MSWLFs located in Approved States to utilize a final cover design which the Director has determined meets the performance standard in § 258.60(b) [56 FR 51040; Oct. 9, 1991]. The final cover requirement for MSWLFs which stop receiving waste prior to the effective date is consistent with many State programs, thus, EPA believes that qualifying small landfills which stop receiving waste prior to October 9, 1997 may utilize any of the final cover designs, including an Approved State alternative for the infiltration layer as specified in today's rule, which meet the performance standards in § 258.60(b).

D. Financial Assurance

Subpart G of Part 258 contains the Financial Assurance requirements applicable to MSWLFs. As noted in the preamble to the Revised Criteria for Municipal Solid Waste Landfills (56 FR 51104; October 9, 1991), EPA has determined that financial responsibility is a necessary component of the regulatory program and is essential to protecting human health and the environment. Further, EPA considered its requirements as the minimum that it considered necessary. ''The financial assurance requirements in today's rule have been structured such that the assurance is required only for costs of activities that are certain to be needed, and the amount of financial assurance is based on site-specific estimates of the costs of closure, post-closure care, and corrective action. Less stringent financial assurance requirements would not ensure that adequate funds will be available when needed to cover these costs.'' (56 FR 51105; October 9, 1991). Having adequate funds available is necessary since, ''Technical requirements are effective in protecting human health and the environment only if funds are available in a timely manner to conduct these activities'' (*ibid*). EPA was and remains concerned that a general relaxation of the standards beyond the considerable flexibility EPA is already providing might not be protective.

However, EPA's rules allow States to adopt a range of approaches that would also be protective and promote compliance by all owners and operators. In establishing its financial assurance regulations for MSWLFs, EPA provided several federally specified mechanisms, and the option for States to determine mechanisms that would meet a highly flexible performance standard. This performance standard allows the Director of an Approved State to approve any financial mechanism that (a) ensures sufficient coverage, (b) ensures funds are available in a timely fashion when needed, (c) is obtained by the deadline, and (d) is legally valid, binding, and enforceable. EPA encouraged State Directors to consider adopting a broad range of financial approaches to promote compliance by all owners and operators.

Generally, these requirements became effective for MSWLFs on April 9, 1997, although there is a provision that delays the effective date for qualifying small MSWLFs until October 9, 1997. Additionally, EPA recently published an amendment (61 FR 60327; November 27, 1996) to the Criteria that allows the Director of an Approved State to delay the effective date of the Financial Assurance requirements for an additional 12 months beyond the April 9, 1997 effective date, if the owner or operator demonstrates to the Director of an Approved State that the applicable effective date does not provide sufficient time to comply with these requirements and that such a waiver will not adversely affect human health and the environment.

The November 27, 1996, amendment also established a financial test for local governments, including local governments that own or operate small MSWLFs. This test allows a local government to use its financial strength to avoid incurring the expenses associated with the use of a third-party financial instrument (61 FR 60327).

Additionally, this summer EPA intends to promulgate a regulation providing a financial test and corporate guarantee as a mechanism private owners and operators of MSWLFs may use to demonstrate financial assurance. This test will extend to private owners and operators the regulatory flexibility already provided to municipal owners or operators of MSWLFs. These regulations would allow a firm to demonstrate financial assurance by passing a financial test. For firms that qualify for the financial test, this mechanism will be less costly than the use of a third party financial instrument such as a trust fund or a surety bond.

EPA believes that considerable additional flexibility has been or soon will be afforded to the Director of Approved States. These changes include the following;

a. the additional flexibility to extend the effective date for financial assurance, as described above,

b. the local government test, and

c. the corporate financial test.

These flexibilities coupled with the flexibility available to Directors of Approved States in the Criteria for MSWLFs promulgated on October 9, 1991, also described above, provide the flexibility contemplated by the LDPFA. Thus, today's rule does not include any additional changes to the Financial Assurance requirements. As described above, EPA will establish an additional area of flexibility when the corporate financial test is promulgated later this fiscal year.

V. Consideration of Issues Related to Environmental Justice

EPA is committed to addressing environmental justice concerns and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities, and all people live in clean and sustainable communities.

The Agency does not currently have data on the demographics of populations surrounding the small MSWLFs affected by today's rule. The Agency does not believe, however, that today's rule granting additional flexibility to owners and operators of small MSWLFs will have a disproportionately high and adverse environmental or economic impact on any minority or low-income group, or on any other type of affected community. In addition, any minority group or low-income group affected by alternative requirements will have an opportunity to review and comment on the alternative requirement proposed by the Director of the Approved State prior to its implementation. The Agency believes that this rulemaking will enable some minority and/or low-income communities to continue to be served by a local landfill at the lowest possible cost to residents, including minority and low income residents.

VI. Impact Analysis

A. Executive Order 12866

Under Executive Order 12866, EPA must determine whether a regulatory action is significant and therefore subject to OMB review and the other

provisions of the Executive Order. A significant regulatory action is defined by Executive Order 12866 as one that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or rights and obligations or recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

The Agency believes that this direct final rule does not meet the definition of a major regulation because it does not have an annual effect on the economy of $100 million or more; nor does the rule fall within the other definitional criteria for a significant regulatory action described above. The rule is deregulatory and will result in requirements applicable to specific MSWLFs that are protective of human health and the environment at a lower cost than would be the case without the additional flexibility afforded by these amendments. For this reason, the Agency is not conducting a Regulatory Impact Analysis.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally requires an agency to prepare, and make available for public comment, a regulatory flexibility analysis that describes the impact of a proposed or final rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant adverse impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. The following discussion explains EPA's determination.

Implementation of the various requirements imposes increased costs on small MSWLFs and the small communities, including small Indian Tribes, that they serve. MSWLFs that dispose of 20 TPD of waste generally serve populations of 10,000 persons or less (based on a waste generation rate of 4 pounds per person per day). Because these owners/operators may lack practicable solid waste management alternatives, such as the option of joining regional waste management systems, these communities may have been required to absorb higher than necessary costs of compliance in the absence of the additional flexibility afforded by today's rule.

The effect of this rule is to provide small entities with additional flexibility to meet the requirements of Part 258. The rule does not impose new burdens on small entities. Therefore, pursuant to 5 U.S.C. 605b, I hereby certify that this rule will not have a significant adverse impact on a substantial number of small entities. This rule, therefore, does not require a regulatory flexibility analysis.

C. Paperwork Reduction Act

The Agency has determined that there are no new reporting, notification, or recordkeeping provisions associated with today's final rule.

D. Executive Order 12875

Under Executive Order 12875, Federal agencies are charged with enhancing intergovernmental partnerships by allowing State and local governments the flexibility to design solutions to problems the citizenry is facing. Executive Order 12875 calls on Federal agencies to either pay the direct costs of complying with Federal mandates or to consult with representatives of State, local, or Tribal governments prior to formal promulgation of the requirement. The Executive Order also relates to increasing flexibility for State, Tribal, and local governments through waivers. Today's notice grants additional flexibility in complying with the MSWLF criteria, does not impose unfunded federal mandates on State, Tribal, and local governments, and is being undertaken to ensure that EPA is providing maximum flexibility to States, Tribes, and local governments. Additionally, the Agency has maintained a dialog with States, Tribes, and local governments regarding ways of ensuring appropriate flexibility while maintaining protection of human health and the environment for small MSWLFs. Therefore, the Agency believes that this consultation with States, Tribes, and local governments, in addition to the public comment period provided in the proposed rules section of today's **Federal Register**, satisfies the requirement of this Executive Order.

E. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of regulatory actions on State, local, and Tribal governments, and the private sector. Under Section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objective of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. In fact, today's rule provides States with additional flexibility that will lower the cost of compliance with the Criteria for Municipal Solid Waste Landfills. In accordance with section 203, EPA has worked closely with the States in the development of this rule.

F. Small Business Regulatory Enforcement Act of 1996 (SBREFA)

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Act of 1996, before this

rule takes effect, EPA has submitted a report containing this rule and other required information to the U.S. Senate, U.S. House of Representatives, and the Comptroller General of the General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 258

Environmental protection, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: July 23, 1997.

Carol M. Browner,

Administrator.

For reasons set out in the preamble, Title 40 of the Code of Federal Regulations is amended as follows:

PART 258—CRITERIA FOR MUNICIPAL SOLID WASTE LANDFILLS

1. The authority citation for part 258 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a), 6944(a) and 6949a(c); 33 U.S.C. 1345 (d) and (e).

2. Section 258.21 is amended by adding a new paragraph (d) to read as follows:

§ 258.21 Cover material requirements.

* * * * *

(d) The Director of an Approved State may establish alternative frequencies for cover requirements in paragraphs (a) and (b) of this section, after public review and comment, for any owners or operators of MSWLFs that dispose of 20 tons of municipal solid waste per day or less, based on an annual average. Any alternative requirements established under this paragraph must:

(1) Consider the unique characteristics of small communities;

(2) Take into account climatic and hydrogeologic conditions; and

(3) Be protective of human health and the environment.

3. Section 258.23 is amended by adding a new paragraph (e) to read as follows:

§ 258.23 Explosive gases control.

* * * * *

(e) The Director of an Approved State may establish alternative frequencies for the monitoring requirement of paragraph (b)(2) of this section, after public review and comment, for any owners or operators of MSWLFs that dispose of 20 tons of municipal solid waste per day or less, based on an annual average. Any alternative monitoring frequencies established under this paragraph must:

(1) Consider the unique characteristics of small communities;

(2) Take into account climatic and hydrogeologic conditions; and

(3) Be protective of human health and the environment.

4. Section 258.60 is amended by adding a new paragraph (b) (3) to read as follows:

§ 258.60 Closure criteria.

* * * * *

(b) * * *

(3) The Director of an Approved State may establish alternative requirements for the infiltration barrier in a paragraph (b)(1) of this section, after public review and comment, for any owners or operators of MSWLFs that dispose of 20 tons of municipal solid waste per day or less, based on an annual average. Any alternative requirements established under this paragraph must:

(i) Consider the unique characteristics of small communities:

(ii) Take into account climatic and hydrogeologic conditions; and

(iii) Be protective of human health and the environment.

* * * * *

[FR Doc. 97–19942 Filed 7–28–97; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[F–97–FLXP–FFFFF–5865–4]

RIN 2050–AE24

Revisions to Criteria for Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Land Disposal Program Flexibility Act of 1996 (LDPFA) directed the Administrator of the U.S. Environmental Protection Agency (EPA) to provide additional flexibility to the Director of Approved States for the owners and operators of landfills that receive 20 tons or less of municipal solid waste per day. The additional flexibility pertains to alternative frequencies of daily cover, frequencies of methane monitoring, infiltration layers for final cover, and means for demonstrating financial assurance. The additional flexibility will allow the owners and operators of small municipal solid waste landfills (MSWLFs) the opportunity to reduce the cost of MSWLF operation while still protecting human health and the environment. This proposal recognizes, as did Congress in enacting LDPFA, that these decisions are best made at the State and local level and, therefore, offers this flexibility to approved States.

In the final rules Section of today's **Federal Register**, EPA is promulgating this amendment as a final rule without prior proposal because EPA views this as a noncontroversial action that in effect, codifies a legislative directive. Thus, we anticipate no adverse comments. A detailed rationale for the amendment is set forth in the preamble to the direct final rule. If no adverse comments are received in response to this proposal, no further activity is contemplated regarding this proposed rule. If EPA receives adverse comments, EPA will withdraw the final rule and all public comments received will be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action.

DATES: Comments on this proposed rule must be received on or before August 28, 1997. An adverse comment will be considered to be any comment substantively criticizing the proposal on a basis not already provided to EPA in comment.

ADDRESSES: Commenters must send an original and two copies of their comments referencing docket number F–97–FLXP–FFFFF to: RCRA Docket Information Center, Office of Solid Waste (5305G), U.S. Environmental Protection Agency Headquarters (EPA, HQ), 401 M Street, SW, Washington, DC 20460. Hand deliveries of comments should be made to the Arlington, VA, address below. Comments may also be submitted electronically through the Internet to: rcra-docket@epamail.epa.gov. Comments in electronic format should also be identified by the docket number F–97–FLXP–FFFFF. All electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Commenters should not submit electronically any confidential business information (CBI). An original and two copies of CBI must be submitted under separate cover to: RCRA CBI Document Control Officer, Office of Solid Waste (5305W), U.S. EPA, 401 M Street, SW, Washington, DC 20460.

Public comments and supporting materials are available for viewing in the RCRA Information Center (RIC), located at Crystal Gateway I, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling 703 603–9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page. The index and some supporting materials are available electronically. See the **SUPPLEMENTARY INFORMATION** section for information on accessing them.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at 800 424–9346 or TDD 800 553–7672 (hearing impaired). In the Washington, DC, metropolitan area, call 703 412–9810 or TDD 703 412–3323.

For more detailed information on specific aspects of this rulemaking, contact Mr. Allen J. Geswein, U. S. Environmental Protection Agency, Office of Solid Waste (5306W), 401 M Street, SW, Washington, DC 20460, 703 308–7261, [GESWEIN.ALLEN @EPAMAIL.EPA.GOV].

SUPPLEMENTARY INFORMATION: The index and the following supporting materials are available on the Internet:

Memorandum to: RCRA Docket

From: Allen J. Geswein, Environmental Engineer

Subject: Daily Cover Requirements for MSWLFs

Memorandum to: RCRA Docket

From: Allen J. Geswein, Environmental Engineer

Subject: Landfill Gas Monitoring Requirements for MSWLFs

Memorandum to: RCRA Docket

From: Allen J. Geswein, Environmental Engineer

Subject: Infiltration Layer Requirements for MSWLFs

Memorandum to: RCRA Docket

From: Allen J. Geswein, Environmental Engineer

Subject: Financial Assurance Requirements for MSWLFs

Follow these instructions to access the information electronically:

WWW: http://www.epa.gov/epaoswer/nonhazardous waste

FTP: ftp.epa.gov

Login: anonymous

Password: your Internet address

Files are located in /pub/gopher/OSWRCRA.

The official record for this action will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into paper form and place them in the official record, which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in **ADDRESSES** at the beginning of this document.

EPA responses to comments, whether the comments are written or electronic, will be in a notice in the **Federal Register** or in a response to comments document placed in the official record for this rulemaking. EPA will not immediately reply to commenters electronically other than to seek clarification of electronic comments that may be garbled in transmission or during conversion to paper form, as discussed above.

Regulated Entities

Entities potentially regulated by this action are public or private owners or operators of municipal solid waste landfills (MSWLFs) that dispose of 20 tons or less of municipal solid waste per day, based on an annual average. Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Owners or operators of small MSWLFs
Municipal Governments	Owners or operators of small MSWLFs

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities the EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility would be regulated by this action, you should carefully examine the applicability criteria in the proposal. If you have questions regarding the applicability of this action to a particular facility, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Preamble Outline

I. Authority

The Agency is proposing these regulations under the authority of sections 1008(a)(3), 2002(a), 4004(a), and 4010(c) of the Resource Conservation and Recovery Act (RCRA), as amended, 42 U.S.C. 6907(a)(3), 6912(a), 6944(a), and 6949a(c).

II. Background

As set out in detail in the related direct final rule, EPA is proposing to issue rules that grant the Director of an Approved State the flexibility to establish alternative requirements for certain criteria for small MSWLFs. EPA is promulgating revisions to existing criteria which would allow a Director of an Approved State, after public review and comment, to establish for small MSWLFs, alternative frequencies of daily cover application, frequencies of methane gas monitoring, and infiltration layers for final cover. Alternative means for demonstrating financial assurance for small MSWLFs are also discussed in the related direct final rule. When establishing these alternative requirements, the Director of an Approved State must, after public review and comment, consider the unique characteristics of small communities, take into account climatic and hydrogeologic conditions, and ensure that any alternative standard is protective of human health and the environment.

III. Additional Information

For additional information, see the corresponding direct final rule published in the final rules section of this **Federal Register**. All persons who may wish to comment should review the preamble discussion in the direct final rule **Federal Register** notice.

IV. Consideration of Issues Related to Environmental Justice

EPA is committed to addressing environmental justice concerns and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities, and all people live in clean and sustainable communities.

The Agency does not currently have data on the demographics of populations surrounding the small MSWLFs affected by today's rule. The Agency does not believe, however, that today's rule granting additional flexibility to owners and operators of small MSWLFs will have a disproportionately high and adverse environmental or economic impact on any minority or low-income group, or on any other type of affected community. In addition, any minority group or low-income group affected by alternative requirements will have an opportunity to review and comment on the alternative requirement proposed by the Director of the Approved State prior to its implementation. The Agency believes that this rulemaking will enable some minority and/or low-income communities to continue to be served by a local landfill at the lowest possible cost to residents, including minority and low income residents.

V. Impact Analysis

A. Executive Order 12866

Under Executive Order 12866, EPA must determine whether a regulatory action is significant and therefore subject to OMB review and the other provisions of the Executive Order. A significant regulatory action is defined by Executive Order 12866 as one that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or rights and obligations or recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

The Agency believes that this proposed rule does not meet the definition of a major regulation because it does not have an annual effect on the economy of $100 million or more; nor does the rule fall within the other definitional criteria for a significant regulation described above. The proposed rule is deregulatory and will result in requirements applicable to specific MSWLFs that are protective of human health and the environment at a lower cost than would be the case without the additional flexibility afforded by these amendments. For this reason, the Agency is not conducting a Regulatory Impact Analysis.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally requires an agency to prepare, and make available for public comment, a regulatory flexibility analysis that describes the impact of a proposed or final rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant adverse impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small

entities. The following discussion explains EPA's determination.

Implementation of the various requirements imposes increased costs on small MSWLFs and the small communities, including Tribes, that they serve. MSWLFs that dispose of 20 TPD of waste generally serve populations of 10,000 persons or less (based on a waste generation rate of 4 pounds per person per day). Because these owners/operators may lack practicable solid waste management alternatives, such as the option of joining regional waste management systems, these communities may have been required to absorb higher than necessary costs of compliance in the absence of the additional flexibility afforded by today's proposed rule.

The effect of this proposed rule is to provide small entities with additional flexibility to meet the requirements of Part 258. The proposal would not impose any new burdens on small entities. Therefore, pursuant to 5 U.S.C. 605(b), I certify that this proposed rule would not have a significant adverse impact on a substantial number of small entities. This proposed rule, therefore, does not require a regulatory flexibility analysis.

C. Paperwork Reduction Act

The Agency has determined that there are no new reporting, notification, or recordkeeping provisions associated with today's proposed rule.

D. Executive Order 12875

Under Executive Order 12875, Federal agencies are charged with enhancing intergovernmental partnerships by allowing State and local governments the flexibility to design solutions to problems the citizenry is facing. Executive Order 12875 calls on Federal agencies to either pay the direct costs of complying with Federal mandates or to consult with representatives of State, local, or tribal governments prior to formal promulgation of the requirement. The Executive Order also relates to increasing flexibility for State, Tribal, and local governments through waivers. Today's proposed rule grants additional flexibility in complying with the MSWLF criteria, does not impose unfunded federal mandates on State, Tribal, and local governments, and is being undertaken to ensure that EPA is providing maximum flexibility to States, Tribes, and local governments. Additionally, the Agency has maintained dialog with States, Tribes, and local governments regarding ways of ensuring appropriate flexibility while maintaining protection of human health and the environment for small MSWLFs. Therefore, the Agency believes that this consultation with States, Tribes, and local governments, in addition to the public comment period provided in the proposed rules Section of today's **Federal Register**, satisfies the requirement of this Executive Order.

E. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of regulatory actions on State, local, and Tribal governments, and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objective of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this proposed rule does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. In fact, today's proposed rule provides States with additional flexibility that would lower the cost of compliance with the Criteria for Municipal Solid Waste Landfills. In accordance with section 203, EPA has shared this proposal with State governments and asked for comment.

List of Subjects in 40 CFR Part 258

Environmental protection, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: July 23, 1997.

Carol M. Browner,

Administrator.

[FR Doc. 97–19941 Filed 7–28–97; 8:45 am]

BILLING CODE 6560–50–U

Federal Register

Tuesday
July 29, 1997

Part VIII

The President

Proclamation 7013—Death of William J. Brennan, Jr.

Federal Register
Vol. 62, No. 145
Tuesday, July 29, 1997

Presidential Documents

Title 3—

The President

Proclamation 7013 of July 24, 1997

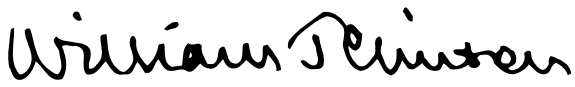
Death of William J. Brennan, Jr.

By the President of the United States of America

A Proclamation

As a mark of respect for the memory of William J. Brennan, Jr., former Associate Justice of the Supreme Court of the United States, I hereby order, by the authority vested in me as President of the United States of America by section 175 of title 36 of the United States Code, that the flag of the United States shall be flown at half-staff upon all public buildings and grounds, at all military posts and naval stations, and on all naval vessels of the Federal Government in the District of Columbia and throughout the United States and its Territories and possessions until sunset on the day of interment. I also direct that the flag shall be flown at half-staff for the same period at all United States embassies, legations, consular offices, and other facilities abroad, including all military facilities and naval vessels and stations.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fourth day of July, in the year of our Lord nineteen hundred and ninety-seven, and of the Independence of the United States of America the two hundred and twenty-second.



[FR Doc. 97–20098
Filed 7–28–97; 8:45 am]
Billing code 3195–01–P

Federal Register

Tuesday
July 29, 1997

Part IX

The President

Federal Register
Vol. 62, No. 145
Tuesday, July 29, 1997

Presidential Documents

Title 3—

The President

Proclamation 7014 of July 25, 1997

National Korean War Veterans Armistice Day, 1997

By the President of the United States of America

A Proclamation

On July 27, 1953, a negotiated cease-fire brought an end to the Korean War and to some of the most savage fighting in the history of America's Armed Forces. More than 54,000 Americans lost their lives, more than 103,000 were wounded, and thousands more were listed as missing in action. To a nation still recovering from the terrors and hardships of World War II, this conflict was a harsh reminder that freedom still had enemies at large in the world.

But the Korean War taught us that free nations could work together in partnership through the United Nations, standing firm against tyranny and in defense of liberty. We were reminded once again of the skill, courage, and indomitable spirit of our men and women in uniform. We learned that the American people were tough enough and determined enough to prevail in the long struggle of the Cold War.

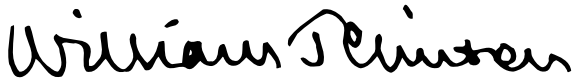
Our victory in that struggle had its roots in the Korean War, and we owe our veterans of that conflict a profound debt of gratitude. Many of them were still scarred from the battles of World War II when they answered the call to duty in Korea. They fought a different kind of war in an unfamiliar land, facing a new and fiercely determined enemy. There they proved to all the enemies of freedom, and to the world, that America's commitment to liberty, democracy, and human rights was not only one of words, but also one of deeds.

Etched into the eastern wall of the Korean War Veterans Memorial in our Nation's Capital is the simple sentence, ''Freedom Is Not Free.'' On this day we honor those who recognized the truth of that inscription and were willing to pay freedom's price with their own lives. We salute our men and women in uniform who served so valiantly in the Korean War, and we remember with sorrow and with pride all those who never came home.

The Congress, by Public Law 104–19 (36 U.S.C. 169m), has designated July 27, 1997, as ''National Korean War Veterans Armistice Day'' and has authorized and requested the President to issue a proclamation in observance of this day.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim July 27, 1997, as National Korean War Veterans Armistice Day. I call upon all Americans to observe this day with appropriate ceremonies and activities that honor and give thanks to our Nation's distinguished Korean War veterans. I also ask Federal departments and agencies, interested groups, organizations, and individuals to fly the American flag at half-staff on July 27, 1997, in memory of the Americans who died as a result of their service in Korea.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fifth day of July, in the year of our Lord nineteen hundred and ninety-seven, and of the Independence of the United States of America the two hundred and twenty-second.



[FR Doc. 97–20150
Filed 7–28–97; 11:30 am]
Billing code 3195–01–P

Presidential Documents

Proclamation 7015 of July 25, 1997

Parents' Day, 1997

By the President of the United States of America

A Proclamation

There are few experiences in life more challenging or more rewarding than being a parent. Holding their child for the first time, parents suddenly realize that they are totally responsible for this small person entrusted to their care. On Parents' Day, we pay tribute to these quiet heroes among us—the mothers and fathers who make a lifetime commitment to their children.

Parents work hard to meet their children's need for food, shelter, clothing, and protection; but more important, they give their daughters and sons the deep and abiding love, guidance, attention, and encouragement that empowers them with the values and self-esteem to succeed in life. Parents love their children as they are, yet still help them to dream big dreams about who they can become.

The more we learn about our children, the more we realize the importance of good parenting. As we learned at the recent White House Conference on Early Childhood Development and Learning, the first few years of life are crucial to a child's emotional, social, and intellectual development. As their children's first and most influential teachers, parents play an immeasurably important role in helping their sons and daughters grow into happy and healthy adulthood.

The responsibilities of parenthood have become even more challenging in today's complex world. In many American families, both parents must work, struggling to balance the demands of job, home, and family. This balancing act is even harder for single parents, who must face the challenge of raising their children alone. In our mobile society, parents are often less able to rely on an extended family to help them provide the care and attention their children need. And today's mothers and fathers must protect their children from the ever-present threats of drugs, gangs, guns, violence, and unhealthy influences in the media and on the Internet.

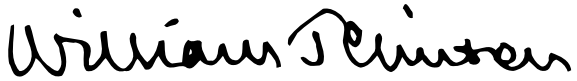
Recognizing that good parents are the foundation of our society, my Administration has strived for the past 4 years to give parents the help they need to meet their responsibilities. I signed into law the Family and Medical Leave Act of 1993, and we are now proposing an expansion of that legislation to allow workers up to 24 hours of unpaid leave each year to meet family obligations. We are fighting to make our neighborhoods safer and drug-free and to reduce juvenile crime. We have expanded and improved Head Start to help parents prepare their young children to enter school ready to learn, and we have created an Early Head Start Program for children age 3 and under. We succeeded in requiring the installation of the V-chip and in helping to develop a voluntary ratings system on television so that parents can better protect their children from inappropriate material. And we are working with the computer industry to provide family-friendly controls that will give parents similar tools to use on the Internet.

As we observe Parents' Day this year, I urge all Americans to join me in paying tribute to the millions of mothers and fathers—biological and adoptive, foster parents and stepparents—whose boundless love and selfless efforts are building a better life for their children and for our nation. Let

us repay that love and effort by striving, in our neighborhoods, schools, businesses, community and church organizations, and in government at every level, to help parents fulfill their awesome responsibilities and create a brighter future for America.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States and consistent with Public Law 103–362, do hereby proclaim Sunday, July 27, 1997, as Parents' Day. I invite the States, communities, and the people of the United States to join together in observing this day with appropriate ceremonies and activities to honor our Nation's parents.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fifth day of July, in the year of our Lord nineteen hundred and ninety-seven, and of the Independence of the United States of America the two hundred and twenty-second.



[FR Doc. 97–20151
Filed 7–28–97; 11:30 am]
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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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Agricultural Marketing Service

Fresh cut flowers and fresh cut greens promotion and information order; assessment removal; published 7-28-97

DEFENSE DEPARTMENT

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Truth in negotiations and related changes; published 7-29-97

ENVIRONMENTAL PROTECTION AGENCY

Air quality implementation plans; approval and promulgation; various States:

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Texas; published 5-30-97

Hazardous waste program authorizations:

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Program Fraud Civil Remedies Act of 1986; implementation:

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AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

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HOUSING AND URBAN DEVELOPMENT DEPARTMENT

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Housing assistance payments (Section 8)—

Fair market rent schedules for rental certificate, loan management, property disposition, moderate rehabilitation, and rental voucher programs; comments due by 7-29-97; published 4-30-97

INTERIOR DEPARTMENT

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Outer Continental Shelf; geological and geophysical explorations; comments due by 7-29-97; published 5-28-97

JUSTICE DEPARTMENT

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Byproduct material; domestic licensing:

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